Nevada Board of Health Meeting December 3 2021

Agenda Item 3 – Health reports

State of Nevada

"Safe and Effective Covid -19 Vaccines"

This is FALSE TO MANY INJURED INDIVIDUALS

HEALTH IMPACTS:

Today DEC/2/2021 there are **10,191 COVID-19 vaccine related deaths reported on CDC Vaccine Adverse reporting** system. When you **ADD life threatening and permanent disability the total is 30,121.** This is **only the United States**.

ALSO, PER CDC VAERS WEBSITE Healthcare providers are **required by law** to report to VAERS: HOWEVER, MOST HOSPITALS DO NOT REPORT TO VAERS. CDC also states **less than 7% of actual adverse events are reported to VAERS revealing a gruesome "grave danger" from these vaccines.**

PER CDC WEBPAGE https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html - Case numbers of 1,822 Myocarditis or pericarditis reported from 12-29 years old (young people!), 1,059 of those have been confirmed so far but "**still investigating**." **10,104 deaths but "still investigating**." Anaphylaxis, thrombosis, Gillian barre (nerve cell damage causing paralysis and muscle weakness), death, blood clots. 3100 Cases reported to HRSA but zero payouts so far. Many pharmaceuticals have been taken off the market for less than 100 deaths, why not this one?

*****FDA NEEDS UNTIL 2076 TO ANALYZE ALL VACCINE DATA *** This makes the Nuremberg code applicable as these vaccines are experimental http://www.cirp.org/library/ethics/nuremberg/** Every manufacturer states clearly on their vaccine page that these are NOT FDA approved.

However Pfizer has had to release 500 pages by court order so I have attached that to these comments showing the over 10,000 adverse events they knew about in February.

ADVERSE EVENTS FROM VACCINES MOST OF WHICH ARE BEING CENSORED BY SOCIAL MEDIA AND NEWS OUTLETS: (compensation payouts are zero-even for original trial victims)

https://thefederalist.com/2021/06/29/twitter-censors-video-of-mother-describing-daughters-covid-19-vaccine-side-effects/

https://www.linkedin.com/posts/thomas-w-jones-jr-a7210b61_vaccine-injury-attorney-fda-asks-judge-to-activity-6867249223017074688-Bdcm

https://www.abc4.com/news/pdf/pdf-life-altering-injuries-letter-to-cdc-regarding-covid-19-vaccine/ - **PLEA LETTER FROM US SENATORS**

https://www.cnn.com/2021/10/05/health/washington-blood-clot-vaccine-death/index.html

https://www.nbcnews.com/news/us-news/virginia-woman-dies-shortly-after-receiving-coronavirus-vaccine-n1256880

https://www.dailymail.co.uk/news/article-9357521/Physical-therapist-28-dies-two-days-taking-COVID-19-vaccine.html

https://abc7.com/moderna-vaccine-covid-side-effects-orange-county-coroner-death-investigation/10562182/

https://news.yahoo.com/man-dies-blood-clot-moderna-vaccine-210012580.html

https://www.msn.com/en-us/health/medical/13-year-old-dies-in-sleep-after-receiving-pfizer-covid-vaccine-cdc-investigating/ar-AALHXDL

https://pubmed.ncbi.nlm.nih.gov/34664804/

"Continuous compliance with face-mask-use …. Other respiratory viruses such as influenza and other gastrointestinal infections such as Norovirus"

IT IS PROPOSTEROUS TO THINK WE WILL PROTECT PEOPLE FROM EVERY VIRUS.

SO NEVADA IS SETTING US UP FOR PERPETUAL MASK WEARING

THE EFFICACY AND ADVERSE AFFECTS OF MASK WEARING ON HUMAN HEALTH AND PSYCOLOGY WHEN BEING MANDATED TO WEAR THEM FOR THESE EXTENSIVE LONG PERIODS OF A WORKDAY HOWEVER CAN LEAD TO LONG TERM DAMAGE PHYSICALLY AND PSYCOLOGICALLY BASED ON THESE STUDIES

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8072811/ - We not only found evidence in the reviewed mask literature of potential long-term effects, but also evidence of an increase in direct short-term effects with increased mask-wearing time in terms of cumulative effects for: carbon dioxide retention, drowsiness, headache, feeling of exhaustion, skin irritation (redness, itching) and microbiological contamination (germ colonization) [19,22,37,66,68,69,89,91,92].

Overall, the exact frequency of the described symptom constellation MIES (mask induced exhaustion syndrome) in the mask-using populace remains unclear and cannot be estimated due to insufficient data.

Theoretically, the mask-induced effects of the drop in blood gas oxygen and increase in carbon dioxide extend to the cellular level with induction of the transcription factor HIF (hypoxia-induced factor) and increased inflammatory and cancer-promoting effects [160] and can, thus, also have a negative influence on pre-existing clinical pictures.

In any case, the MIES potentially triggered by masks (Figure 3 and Figure 4) contrasts with the WHO definition of health: "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." [178].

IT IS IMMINENT THAT STUDIES TAKE PLACE REGARDING THE GRAVE DANGER VERSUS BENEFIT OF LONG TERM MASK WEARING IN COMPARISON TO COVID-19 HEALTH DANGERS ESPECIALLY IN THE HEALTHY POPULATION.

Masks creating an environmental threat : https://news.cgtn.com/news/2020-09-11/Disposable-masks-may-pose-environmental-threat--TH9omxdanu/index.html

Masks and gloves creating an environmental hazard: https://www.cnn.com/2020/04/21/us/coronavirus-ppe-masks-gloves-environment-hazard-trnd/index.html

https://news.un.org/en/story/2020/07/1069151 (United Nations article- pollution and toxicity of mask usage)

"Universal vaccination for all eligible people its the only way to control the COVID-19 pandemic"

ARE YOU ALL READING AND BUYING THIS GARBAGE?

I have attached studies that have been hidden by main search engines but you can find everything by using the Duck Duck go filter on Google **about how you all have made it practically impossible to get these proven life saving medications** such as Ivermectin which in fact was successful against COVID and Chloriquine. Yet you are allowing treatment with Remdesivir which causes renal failure and death.

"Natural and Vaccine induced immunity seem to be waning"

HOW DO YOU KNOW ANYTHING ABOUT NATURAL IMMUNITY?

I HAVE ATTACHED A FOIA REQUEST LETTER FROM CDC THAT **THEY ARE NOT COLLECTING ANY DATA ON NATURAL IMMUNITY**

I have also attached studies showing 13x better immunity naturally as well as long immunity over time.

"expansion of testing, randomized workplace testing"

THIS IS ALL AGAINST THE LAW EVEN WITH THE CHANGES TO THE EOCC WITH COVID- EITHER YOU TEST EVERYONE, VACCINATED, UNVACCINATED AND SYMPTOMATIC OR YOU TEST NO ONE!

TESTING ASYMPTOMATIC EMPLOYEES IS ALSO AGAINST THE EEOCC **THE PANDEMIC MODIFICATIONS TO THE EEOC MADE IN 2020 * DO NOT EMPLOY MANADATORY TESTING FOR AN ASYMPTOMATIC PERSON** :

https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act

PROHIBITED BY EEOC - A **"medical examination"** is a procedure or test that seeks information about an individual's physical or mental impairments or health.[(14)] Whether a procedure is a medical examination under the ADA is determined by considering factors such as whether the test involves the use of medical equipment; whether it is invasive; whether it is designed to reveal the existence of a physical or mental impairment; and whether it is given or interpreted by a medical professional. **During employment:** The ADA prohibits employee disability-related inquiries or medical examinations unless they are job-related and consistent with business necessity. Generally, a disability-related inquiry or medical examination of an employee is job-related and consistent with business necessity when an employer has a reasonable belief, based on objective evidence, that:

1. An employee's ability to perform essential job functions will be impaired by a medical condition; or
2. An employee will pose a direct threat due to a medical condition.
3.

"The DPBH recommends vaccination for all eligible students and staff and testing of all those that are unvaccinated"
"testing a random sample of at least 10% of staff and **students who are not fully vaccinated**"

THIS IS DISCRIMINATORY – YOU HAVE TO EITHER TEST ONLY SYMPTOMATIC PEOPLE OR EVERYONE BY LAW

See studies attached also regarding viral loads the same in both vaccinated and unvaccinated, and vaccinated can spread and contract just the same

REFER TO UC DAVIS CA STUDY HERE https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v1.full

No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant

ALSO: CDC DIRECTOR WALLENSKY STATED BACK IN JULY **https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html**

"Today, some of those data were published in CDC's *Morbidity and Mortality Weekly Report (MMWR)*, demonstrating that Delta infection resulted in similarly high SARS-CoV-2 viral loads in vaccinated and unvaccinated people. High viral loads suggest an increased risk of transmission and raised concern that, unlike with other variants, vaccinated people infected with Delta can transmit the virus. This finding is concerning and was a pivotal discovery leading to CDC's updated mask recommendation. The masking recommendation was updated to ensure the vaccinated public would not unknowingly transmit virus to others, including their unvaccinated or immunocompromised loved ones."

***THESE STUDIES BELOW SHOW **INACCURACY AND BIAS IN TESTING** CAUSING UNFAIR DISCRIMINATORY QUARANTINES, LOSS OF WAGES, UNNESSESARY COSTS TO EMPLOYEES AND EMPLOYERS FOR TESTING WITHOUT CAUSE:

FDA - https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory

"The FDA reminds clinical laboratory staff and health care providers about the risk of false positive results with all laboratory tests. Laboratories should expect some false positive results to occur even when very accurate tests are used for screening large populations"

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7934325/ - IMPACTS OF FALSE POSITIVES (ref 12.21)

Unnecessary isolation of individuals and quarantining of close contacts with financial and psychological strains (ref 16.22), Unnecessary contact tracing and testing (ref 23), **Wasteful consumption** of personal protective equipment, Delays in surgical or other procedures (ref 16.23), Prolong hospital stays (ref 16.23), Wasteful consumption of PPE, **Potentially harboring uninfected individuals** with infected individuals in hospitals and congregate living areas with possible nosocomial infection (ref 16.22), possible **exposure to unnecessary medical treatment**, Individual given false sense of security about immunity so may not follow public health guidelines or receive vaccination, impede correct diagnosis for patients with symptoms, Overdiagnosis may **distort epidemiologic statistics** by including false-positives to estimate prevalence, hospitalization, and death rates as well as modeling (eg, some individuals classified as asymptomatic carriers may actually have had a false positive test)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7457918/ **Current studies estimating test performance characteristics have imperfect study design and statistical methods for the estimation of test performance characteristics of SARS-CoV-2 tests. The included studies employ heterogeneous methods and overall have **an increased risk of bias**



Henderson, Nevada

Countermeasures Injury Compensation Program (CICP) Data

Aggregate Data as of October 1, 2021

The Countermeasures Injury Compensation Program (CICP) provides compensation for covered serious injuries or deaths that, based on compelling, reliable, valid, medical and scientific evidence, are found to be directly caused by the administration or use of a covered countermeasure or are determined to meet the requirements of a countermeasure injury table. Temporal association between administration or use of the covered countermeasure and onset of the injury (i.e., the injury occurs a certain time after the administration or use) is not sufficient, by itself, to prove that an injury is the direct result of a covered countermeasure.

It is important to note that the CICP data only captures the alleged countermeasure(s) and the alleged injuries that CICP requesters list on their Request for Benefits forms (RFB) or claim. The countermeasure or injury listed by the requester on the RFB may or may not be consistent with the requester's medical documentation or the injury resulting in compensation. While requesters are required to identify the alleged countermeasure on their RFB form, they are not required to list the specific manufacturer or trade name on their RFB form.

Furthermore, while requesters must submit their RFB form within 1 year from the administration or use of the covered countermeasure, requesters are permitted to submit the necessary medical records and other documentation, such as a copy of a requester's COVID-19 vaccination record, after the RFB is filed. For the majority of COVID-19 countermeasure claims, including COVID-19 vaccine claims, the CICP is still waiting for records and documentation to be submitted.

When was the first CICP claim filed?

The first CICP claim was filed in Fiscal Year (FY) 2010; there are no CICP claims to report on prior to FY 2010.

Is the CICP data available by specific manufacturer or trade name?

The CICP does not maintain its aggregated data concerning alleged countermeasures, including vaccines, by specific manufacturer.

How many claims has the CICP compensated?

The CICP is the payer of last resort and can only reimburse or pay for medical expenses or lost employment income that are not covered by other third-party payers. To date, the CICP has paid compensation for 29 CICP claims, totaling more than $6 million. An additional 10 CICP claims were eligible for compensation after a review of the required medical records and documentation; however, in these cases there were no eligible reported medical expenses or lost employment income for the CICP to compensate.

Has the CICP made any decisions regarding COVID-19 Claims?

As of October 1, 2021, the CICP has not compensated any COVID-19 countermeasures claims. Three COVID-19 countermeasures have been denied compensation because the standard of proof for causation was not met and/or a covered injury was not sustained. One COVID-19 claim has been determined eligible for compensation and is pending a review of eligible expenses.

CICP Data for Fiscal Years 2010 – 2021 (As of October 1, 2021)

Total CICP Claims Filed: **3,649**

- Claims Eligible for Medical Review: **3,556**
  - Eligible for Compensation: **40**
    - Compensated: **29**
    - No Eligible Reported Expenses: **10**
    - Pending: **1**
  - Pending Review or In Review: **3,154**

  - Denied: **362**
    - Requested Medical Records not Submitted: **135**
    - Standard of Proof Not Met and/or Covered Injury not Sustained: **227**
- Claims Ineligible for Medical Review: **93**
  - Missed Filing Deadline: **38**
  - Not CICP Covered Product/ Not Specified: **55**

CICP claims data is provided below in categories pertaining to their status.

Table 1. Alleged COVID-19 Countermeasure Claims Filed as of October 1, 2021

This table displays the alleged countermeasure and alleged injury/death for each COVID-19 countermeasure claim filed as of October 1, 2021. Of the 3,158 COVID-19 countermeasure claims 1,357 allege injuries/deaths from COVID-19 vaccines and 1,801 allege injuries/deaths from other COVID-19 countermeasures.

The CICP does not maintain its aggregated data concerning alleged countermeasures, including vaccines, by specific manufacturer or trade name.

Alleged Countermeasure	Alleged Injury/ Death	Number of Claims
Failure to have infection control programs in place, the failure to have adequate infection control in place, the failure to properly train staff, the failure to provide sufficient staff, the failure to cohort infected and uninfected individuals, the failure to provide PPE to staff and residents, the failure to train on the proper use of PPE, the failure to have adequate procedures in place to deal with infection, the failure to adequately monitor residents for signs of infection, the failure to transfer residents to a higher level of care when needed, the failure to adequately treat residents with COVID, the failure to provide appropriate distancing among residents, the failure to properly report the number of COVID-19 cases and deaths to authorities, and others.	Death	296
Anakinra	Death	1
Antiviral	Death	1
Azithromycin	Death	12
Azithromycin / BiPAP / Ivermectin / Remdesivir	Death	1
Azithromycin / Cefdinir / G-Tube	Death	1
Azithromycin / Cefdinir/ Ibuprofen	Death	1
Azithromycin / Ceftriaxone / Plaquenil	Death	1
Azithromycin / CiPAP	Death	1
Azithromycin / CiPAP / BiPAP	Death	1
Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir	Death	1
Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir / Solu-Medrol	Death	1

Azithromycin / Convalescent Plasma / Hydroxychloroquine / Ivermectin	Death	1
Azithromycin / Dexamethasone / Remdesivir	Death	1
Azithromycin / Dexamethasone / Steroid	Death	1
Azithromycin / Dialysis / Methylprednisolone	Death	1
Azithromycin / Hydroxychloroquine	Death	10
Azithromycin / Hydroxychloroquine / BiPap / Heparin	Death	1
Azithromycin / Hydroxychloroquine / Bolus / Ceftriaxone / Zosyn	Death	1
Azithromycin / Hydroxychloroquine / Dexamethasone	Death	1
Azithromycin / Hydroxychloroquine / Dialysis	Death	1
Azithromycin / Hydroxychloroquine / Dialysis / Solu-Medrol / Tocilizumab	Death	1
Azithromycin / Hydroxychloroquine / Fentanyl / intubation	Death	1
Azithromycin / Hydroxychloroquine / Intubation	Death	5
Azithromycin / Hydroxychloroquine / Methylprednisolone / Tocilizumab	Death	1
Azithromycin / Hydroxychloroquine / Remdesivir	Death	1
Azithromycin / Hydroxychloroquine / Respirator	Death	1
Azithromycin / Hydroxychloroquine / Rocephin	Death	1
Azithromycin / Hydroxychloroquine / Solu-Medrol	Death	1
Azithromycin / Hydroxychloroquine / Solu-Medrol / Steroids	Death	1
Azithromycin / Ivermectin / Methylprednisolone	Death	1
Azithromycin / Ivermectin / Methylprednisolone / Remdesivir	Death	22
Azithromycin / Metoprolol	Death	1
Azithromycin / Ondansetron / Cefdinir	Death	1
Azithromycin / Remdesivir	Death	5
BiPap / Convalescent Plasma / Remdesivir	Death	1
BiPap / COVID-19 Medications / Nebulizer	Death	1
BiPAP / CPAP / COVID-19 Medications	Death	1
BiPAP / High Flow Oxygen / Remdesivir	Death	1
BiPap / Hydroxychloroquine / Doxycycline / Ceftriaxone / Heparin	Death	1
BiPAP / Hydroxychloroquine / Ivermectin	Death	1
BiPAP / Hydroxychloroquine / Ivermectin / Remdesivir	Death	3
BiPap / Hydroxychloroquine / Remdesivir	Death	1
BiPAP / Ivermectin / Remdesivir / Vapotherm	Death	1

Chest Compression / Epinephrine / Intubation	Death	1
Chest Compressions / Epinephrine	Death	1
Contrast	Kidney Injury	1
Convalescent Plasma	Death	4
Convalescent Plasma / Remdesivir	Death	4
Convalescent Plasma / Tocilizumab / Zithromax	Death	1
COVID-19 Antivirals / Antibiotics / Anti-inflammatory Medications / Oxygen Therapy	Death	1
COVID-19 Infection	Death	1
COVID-19 Medications	Death	10
COVID-19 Medications / Intubation	Death	1
COVID-19 Medications / Remdesivir	Death	1
COVID-19 Test	Death	1
COVID-19 Test	Perforated Ethymoidal Artery	1
COVID-19 Test	Punctured Brain / CSF	1
COVID-19 Test / Heparin / Supplemental Oxygen / Ultrasound (Duplex)	Brain Injury / Quadriplegia	1
COVID-19 Test / Oxygen	Death	1
COVID-19 Vaccine	Abdominal Pain	2
COVID-19 Vaccine	Abdominal Pain / Chills / Lightheadedness	1
COVID-19 Vaccine	Abdominal Pain / Diarrhea / Nausea / Vomiting / Bloating	1
COVID-19 Vaccine	Abdominal Pain / Leg Pain	1
COVID-19 Vaccine	Abdominal Pain / Muscle and Joint Pain / Chills / Vision Distortion / Retina Puckering	1
COVID-19 Vaccine	Aches / Dehydration / Vomiting	1
COVID-19 Vaccine	Acute Brain Disorder	1
COVID-19 Vaccine	Acute Congestive Heart Failure / Kidney Damage	1
COVID-19 Vaccine	Acute Hearing Loss	1
COVID-19 Vaccine	Acute Inflammatory Demyelinating Polyneuropathy	1
COVID-19 Vaccine	Acute ITP	1

COVID-19 Vaccine	Acute Kidney Injury	1
COVID-19 Vaccine	Acute Non-traumatic Kidney Injury / Pericardial Effusion / Elevated AST	1
COVID-19 Vaccine	Acute Pancreatitis	1
COVID-19 Vaccine	Acute Renal Failure / Rhabdomyolsis / Myositis	1
COVID-19 Vaccine	Acute Saddle Pulmonary Embolism	1
COVID-19 Vaccine	Addison's Disease Crisis	1
COVID-19 Vaccine	Adhesive Capsulitis	2
COVID-19 Vaccine	Adverse Reaction	2
COVID-19 Vaccine	AIDP / GBS	1
COVID-19 Vaccine	Allergic Reaction	44
COVID-19 Vaccine	Allergic Reaction / Burns on Skin	1
COVID-19 Vaccine	Allergic Reaction / Hypersensitivity	1
COVID-19 Vaccine	Allergic Reaction / Panic Attack	1
COVID-19 Vaccine	Allergic Reaction / Peripheral Neuropathy	1
COVID-19 Vaccine	Allergic Reaction / Tachycardia	1
COVID-19 Vaccine	Alopecia Areata	1
COVID-19 Vaccine	Anaphylactic Reaction	10
COVID-19 Vaccine	Anaphylactic Shock	10
COVID-19 Vaccine	Anaphylactic Shock / Face Swelling / Angioedema	1
COVID-19 Vaccine	Anaphylaxis	22
COVID-19 Vaccine	Anaphylaxis / Vasovagal Syncope / AIDP / AMAN	1
COVID-19 Vaccine	Anemia / Heart Problems / Respiratory Problems / Weakness	1
COVID-19 Vaccine	Anxiety / Lack of Sleep / Agitation	1
COVID-19 Vaccine	Anxiety / Ongoing Confusion	1
COVID-19 Vaccine	Anxiety / Rapid Heartbeat / Depression / Chest Pain /	1

	Headache	
COVID-19 Vaccine	Anxiety / Shortness of Breath / Heart Palpitations	1
COVID-19 Vaccine	Appendicitis	6
COVID-19 Vaccine	Arm and Facial Paralysis / Difficulty Breathing	1
COVID-19 Vaccine	Arm and Hand Numbness / Pain	1
COVID-19 Vaccine	Arm and Leg Tingling / Heartburn / Headache	1
COVID-19 Vaccine	Arm and Neck Injury	1
COVID-19 Vaccine	Arm and Shoulder Injury	6
COVID-19 Vaccine	Arm Injury	15
COVID-19 Vaccine	Arm Injury / Fever	1
COVID-19 Vaccine	Arm Injury / Rotator Cuff Tear	1
COVID-19 Vaccine	Arm Leg and Breast Pain / Swollen Lymph Nodes	1
COVID-19 Vaccine	Arm Numbness / Tingling	1
COVID-19 Vaccine	Arm Numbness and Pain	1
COVID-19 Vaccine	Arm Pain	3
COVID-19 Vaccine	Arm Pain and Numbness / Swollen Lymph Nodes / Loss of Sleep	1
COVID-19 Vaccine	Arm Pit and Chest Swelling	1
COVID-19 Vaccine	Arm Pit and Chest Swelling	1
COVID-19 Vaccine	Arm Pit Swelling	1
COVID-19 Vaccine	Arrhythmia / Stroke / Tachycardia	1
COVID-19 Vaccine	Arrhythmia / Tachycardia	1
COVID-19 Vaccine	Aseptic Meningitis	1
COVID-19 Vaccine	Asthma	1
COVID-19 Vaccine	Asthma Attack / Fatigue	1
COVID-19 Vaccine	Atrial Fibrillation	4
COVID-19 Vaccine	Atrial Flutter	1
COVID-19 Vaccine	Autoimmune Disease	1
COVID-19 Vaccine	AV Block	1

COVID-19 Vaccine	Back Pain / Swollen Lymph Nodes	1
COVID-19 Vaccine	Back Pain and Lumps	1
COVID-19 Vaccine	Bacterial Pneumonia	1
COVID-19 Vaccine	Bell’s Palsy	20
COVID-19 Vaccine	Bell’s Palsy / Neuropathy	2
COVID-19 Vaccine	Bleeding Ulcers	1
COVID-19 Vaccine	Blood Clot / Brain Bleed	1
COVID-19 Vaccine	Blood Clot / Fluid in Heart and Lungs	1
COVID-19 Vaccine	Blood Clot / Stroke	1
COVID-19 Vaccine	Blood Clots	37
COVID-19 Vaccine	Blood Clots / Collapsed Lung	1
COVID-19 Vaccine	Blood Clots / Heart Murmur	1
COVID-19 Vaccine	Blood Clots / Leg Cramps / Dizziness	1
COVID-19 Vaccine	Blood Clots / Mucus	1
COVID-19 Vaccine	Blood Clots / Nose Bleed	1
COVID-19 Vaccine	Blood Clots / OVA	1
COVID-19 Vaccine	Blood Pressure / Chest Pain / Shortness of Breath	1
COVID-19 Vaccine	Blood Pressure Drop / Low Heart Rate / Vomiting / Fainting / Dizziness	1
COVID-19 Vaccine	Blood Vessel Break in Brain	1
COVID-19 Vaccine	Blurred Vision / Hives / Itching / Tremors	1
COVID-19 Vaccine	Body Aches	1
COVID-19 Vaccine	Bone Pain / Nausea / Trouble Thinking	1
COVID-19 Vaccine	Bowel Obstruction / Swollen Lymph Nodes	1
COVID-19 Vaccine	Brachial Neuritis	2
COVID-19 Vaccine	Brachial Plexopathy	1
COVID-19 Vaccine	Brain Aneurysm	1
COVID-19 Vaccine	Brain Bleed	1

COVID-19 Vaccine	Brain Bleeding / Blood Clots / Pneumonia	1
COVID-19 Vaccine	Brain Hemorrhage	1
COVID-19 Vaccine	Brain Inflammation / Encephalitis	1
COVID-19 Vaccine	Breakdown of Vital Organs	1
COVID-19 Vaccine	Broken Ankle / Concussion	1
COVID-19 Vaccine	Burning Mouth	1
COVID-19 Vaccine	Bursitis	5
COVID-19 Vaccine	Bursitis / Synovitis / Rotator Cuff Tear	1
COVID-19 Vaccine	Bursting Blood Vessels / Constricted Arteries	1
COVID-19 Vaccine	Cardiac Arrhythmia	1
COVID-19 Vaccine	Cardiac Atrial fibrillation	1
COVID-19 Vaccine	Cardiac Issues / Fatigue / Systemic Lupus Erythematosus	1
COVID-19 Vaccine	Cardiogenic Shock / Pericardial Effusion / Atrial Fibrillation	1
COVID-19 Vaccine	Cardiomyopathy	1
COVID-19 Vaccine	Cellulitis	2
COVID-19 Vaccine	Central and Peripheral Demyelinating Syndrome	1
COVID-19 Vaccine	Central Retinal Artery Occlusion	1
COVID-19 Vaccine	Central Retinal Vein Occlusion	1
COVID-19 Vaccine	Central Venous Sinus Thrombosis	3
COVID-19 Vaccine	Central Venus Thrombocytopenia	1
COVID-19 Vaccine	Cephalic Vein Clot	1
COVID-19 Vaccine	Chest Pain / Chest Cavity Inflammation Around Heart	1
COVID-19 Vaccine	Chest Pain / Fever / Headache / Chills	1
COVID-19 Vaccine	Chest Pain / Headache	1

COVID-19 Vaccine	Chest Pain / Joint Pain / Swelling	1
COVID-19 Vaccine	Chest Pain / Low Oxygen / Pneumonia	1
COVID-19 Vaccine	Chest Pain / Rapid Heartbeat	1
COVID-19 Vaccine	Chest Pain / Shortness of Breath	1
COVID-19 Vaccine	Chest Pains	2
COVID-19 Vaccine	Chest Pains / Fever / Chills / Sore Knees / Insomnia / Loss of Appetite	1
COVID-19 Vaccine	Chest Pressure / Rapid Heart Beat	1
COVID-19 Vaccine	Chest Tightness / Shortness of Breath	1
COVID-19 Vaccine	Chest-Neck Pain / Sweating / Blurred Vision / Spike Blood Pressure	1
COVID-19 Vaccine	Chills / Body Ache / Headache	1
COVID-19 Vaccine	Chills / Shaking / Inability to Breathe and Walk	1
COVID-19 Vaccine	Chronic Cough / Headache / Chest Tightness / Chest and Throat Pain	1
COVID-19 Vaccine	Chronic ITP	1
COVID-19 Vaccine	Chronic Lymphocytic Leukemia	1
COVID-19 Vaccine	CIDP	1
COVID-19 Vaccine	Cognitive Loss / Inflammation in Legs / Irregular Heart Rate	1
COVID-19 Vaccine	Cold Sweats / Sore Muscles / Headaches	1
COVID-19 Vaccine	Colitis / Crohn’s	1
COVID-19 Vaccine	Coma	1
COVID-19 Vaccine	Concussion	1
COVID-19 Vaccine	Concussion / Fainting	1
COVID-19 Vaccine	Concussion / Seizures / Chipped Teeth / Head and Neck Pain	1

COVID-19 Vaccine	Congestive Heart Failure / Enlarged Heart / Heart Palpitations	1
COVID-19 Vaccine	Constant Diarrhea	1
COVID-19 Vaccine	Constant Pain and Numbness in Fingers and Arm	1
COVID-19 Vaccine	Constipation / Indigestion / Abdominal Pain / Fatigue / Dizziness / Headache / Nausea / Vomiting / Chest Pains	1
COVID-19 Vaccine	Cord Compression Myelopathy	1
COVID-19 Vaccine	Cornea Transplant	1
COVID-19 Vaccine	Cough / Cold symptoms	1
COVID-19 Vaccine	Coughing Blood / Severe Chest Pain / Severe Burning Sensation / Blood Clots / Difficulty Breathing	1
COVID-19 Vaccine	COVID Arm / Extreme Fatigue / Joint and Muscle Pain / High Blood Pressure / Heart Irregularities	1
COVID-19 Vaccine	COVID Pneumonia	2
COVID-19 Vaccine	Creutzfeldt-Jacobs	1
COVID-19 Vaccine	Deafness	1
COVID-19 Vaccine	Deafness (Right Side)	1
COVID-19 Vaccine	Death	53
COVID-19 Vaccine	Death / Guillain-Barré Syndrome (GBS)	2
COVID-19 Vaccine	Death / Thrombocytopenia	1
COVID-19 Vaccine	Decreased Heart Rate / Low Blood Pressure	1
COVID-19 Vaccine	Deep Vein Thrombosis (DVT)	9
COVID-19 Vaccine	Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE)	4
COVID-19 Vaccine	Dermatomyositis	1
COVID-19 Vaccine	Difficulty Breathing	3
COVID-19 Vaccine	Difficulty Breathing / Coughing Blood / Swollen	1

	Legs	
COVID-19 Vaccine	Difficulty Breathing / Migraine / Chills / Muscle Pain	1
COVID-19 Vaccine	Difficulty Breathing / Muscle Tension	1
COVID-19 Vaccine	Difficulty Breathing / Nausea / Dizziness / Weakness / Loss of Appetite / Rash / Pain	1
COVID-19 Vaccine	Difficulty Breathing / Nausea / Paralysis / Dizziness	1
COVID-19 Vaccine	Difficulty Breathing / Numbness	1
COVID-19 Vaccine	Difficulty Breathing / Pneumonia / Body Aches / Headaches / Blurred Vision / Dizziness / Weakness	1
COVID-19 Vaccine	Difficulty Breathing and Speaking / Disorientation / Muscle Weakness	1
COVID-19 Vaccine	Disoriented / Unresponsive	1
COVID-19 Vaccine	Diverticulitis	1
COVID-19 Vaccine	Dizziness	1
COVID-19 Vaccine	Dizziness / Broken Leg & Ankle	1
COVID-19 Vaccine	Dizziness / Difficulty Breathing / Foggy Thinking / Dehydration / Numbness / Faintness	1
COVID-19 Vaccine	Dizziness / Head Body Injury	1
COVID-19 Vaccine	Dizziness / Headache / Lethargic / Pressure in Head and Brain	1
COVID-19 Vaccine	Dizziness / Headaches / Facial Paralysis	1
COVID-19 Vaccine	Dizziness / Headaches / Loss of Balance	1
COVID-19 Vaccine	Dizziness / Lightheadedness	1
COVID-19 Vaccine	Dizziness / Loss of Sensation	1

COVID-19 Vaccine	Dizziness / Numbness / Rash	1
COVID-19 Vaccine	Dizziness / Shortness of Breath / Burning Sensation	1
COVID-19 Vaccine	Dizziness / Tachycardia / High Blood Pressure	1
COVID-19 Vaccine	Dizziness / Vomiting / High Blood Pressure	1
COVID-19 Vaccine	Dizziness / Skull Fracture / Concussion	1
COVID-19 Vaccine	DVT / Serum Reaction / Paresthesia / Calculus of Kidney / Gross Hematuria	1
COVID-19 Vaccine	Ear Popping / Confusion / Incoherent / Hard to Concentrate and Focus	1
COVID-19 Vaccine	Elevated Blood Pressure	2
COVID-19 Vaccine	Elevated Blood Pressure / Tremors / Dizziness	1
COVID-19 Vaccine	Elevated Blood Pressure and Heart Rate	2
COVID-19 Vaccine	Elevated Heart Rate / Fever	1
COVID-19 Vaccine	Elevated Heart Rate / Low Blood Pressure	1
COVID-19 Vaccine	Elevated Troponin	1
COVID-19 Vaccine	Elevated Troponin / Decreased Platelet Levels	1
COVID-19 Vaccine	Emotional Distress / Psychiatric Breakdown	1
COVID-19 Vaccine	Encephalopathy	1
COVID-19 Vaccine	Enlarged Lymph Nodes	1
COVID-19 Vaccine	Enlarged Lymph Nodes / Fainted / Dizziness / Nausea / Fatigue / Muscle Aches	1
COVID-19 Vaccine	Eosinophil / Hypoalbuminemia / Thrombocytosis	1
COVID-19 Vaccine	Eosinophilia / Systemic Inflammation	1
COVID-19 Vaccine	Erythema	1
COVID-19 Vaccine	Erythema Nodosum	1

COVID-19 Vaccine	Exacerbation of Pre-Existing Condition	1
COVID-19 Vaccine	Extreme Arm and Leg Pain	1
COVID-19 Vaccine	Extreme Dizziness / Fatigue / Broken Back	1
COVID-19 Vaccine	Extreme Fatigue / Brain Fog	1
COVID-19 Vaccine	Extreme Fatigue / Heart Irregularities	1
COVID-19 Vaccine	Extreme Fatigue / Heart Palpitation	1
COVID-19 Vaccine	Extreme Fatigue / Nausea / Dizziness / Nerve Pain / Abdominal Pain	1
COVID-19 Vaccine	Extreme Fatigue / Shortness of Breath / Elevated Blood Pressure / Left Ventricular Cardiomalogy	1
COVID-19 Vaccine	Extreme Fatigue / Swelling and Pain in Lower Extremities	1
COVID-19 Vaccine	Extreme Joint Pain and Swelling	1
COVID-19 Vaccine	Extreme Swelling	1
COVID-19 Vaccine	Eye Stroke	1
COVID-19 Vaccine	Face Spasms / Hypertension	1
COVID-19 Vaccine	Face Swelling / Inflammation / Leg Bruising / Numbness on Neck, Head, Face and Left Hand Fingers / Severe Kidney Pain / Breast Pain	1
COVID-19 Vaccine	Facial Droop / Tremors	1
COVID-19 Vaccine	Facial Numbness	1
COVID-19 Vaccine	Facial Numbness / Migraine	1
COVID-19 Vaccine	Facial Numbness / Tightness In Chest / High Heart Rate	1
COVID-19 Vaccine	Facial Paralysis	1
COVID-19 Vaccine	Facial Spasms	1
COVID-19 Vaccine	Facial Spasms and	1

	Paralysis	
COVID-19 Vaccine	Facial Swelling	1
COVID-19 Vaccine	Facial Swelling / Weakness / Dizziness / Vision Problems / Severe Hypertension	1
COVID-19 Vaccine	Facial Swelling and Burning / Skin Peeling / Fatigue	1
COVID-19 Vaccine	Fainted	13
COVID-19 Vaccine	Fainted / Allergic Reaction / Hives	1
COVID-19 Vaccine	Fainted / Blood Clots	1
COVID-19 Vaccine	Fainted / Broken Nose	1
COVID-19 Vaccine	Fainted / Broken Teeth	1
COVID-19 Vaccine	Fainted / Chills / Joint Pain / Rash	1
COVID-19 Vaccine	Fainted / Convulsions / Confusion / Throat Swelling	1
COVID-19 Vaccine	Fainted / Dizziness / Weakness	1
COVID-19 Vaccine	Fainted / Elbow Injury	1
COVID-19 Vaccine	Fainted / Headache / Chest Pain / Muscle Spasms / Shortness of Breathe / Weakness / Anxiety / High Blood Pressure	1
COVID-19 Vaccine	Fainted / Hematoma / Concussion	1
COVID-19 Vaccine	Fainted / Seizure	2
COVID-19 Vaccine	Fainted / Seizure / Lost Control of Bladder	1
COVID-19 Vaccine	Fainted / Subdural Hematoma	1
COVID-19 Vaccine	Fainted / Vomiting / Convulsions	1
COVID-19 Vaccine	Fainting	8
COVID-19 Vaccine	Fainting / Broken Ankle	1
COVID-19 Vaccine	Fainting / Chin Laceration	1
COVID-19 Vaccine	Fainting / Difficulty Breathing	1

COVID-19 Vaccine	Fainting / Fatigue / Dizziness / Nausea	1
COVID-19 Vaccine	Fainting / Head Injury	1
COVID-19 Vaccine	Fainting / High Blood Pressure / Low Blood Sugar / Severe Migraines	1
COVID-19 Vaccine	Fainting / Injury to Face	1
COVID-19 Vaccine	Fainting / Mouth Injury	1
COVID-19 Vaccine	Fainting / Vomiting / Convulsions	1
COVID-19 Vaccine	Fatigue / Back Pain / Chest Pain / Severe Headache	1
COVID-19 Vaccine	Fatigue / Body Ache / Headache / Uncontrollable Blood Pressure and Heart Rate	1
COVID-19 Vaccine	Fatigue / Brain Fog	1
COVID-19 Vaccine	Fatigue / Dizziness / Nausea / Diarrhea	1
COVID-19 Vaccine	Fatigue / Dizziness / Nausea / Hallucinations / Brain Fog	1
COVID-19 Vaccine	Fatigue / Dizziness / Severe Leg Pain	1
COVID-19 Vaccine	Fatigue / Fever / Malaise / Dehydration / Acute Kidney Injury / Loss of Appetite / Nausea	1
COVID-19 Vaccine	Fatigue / Heart Palpitations	1
COVID-19 Vaccine	Fatigue / Loss of Appetite / Confusion	1
COVID-19 Vaccine	Fatigue / Nausea / Abdominal Pain / Leg Weakness	1
COVID-19 Vaccine	Fatigue / Nausea / Headache / Fever / Body Ache / Sweating	1
COVID-19 Vaccine	Fatigue / Pain / Nausea / Headache	1
COVID-19 Vaccine	Fatigue / Rash / Pain	1
COVID-19 Vaccine	Fatigue / Sore Armpit / Headache / Elevated Heart Rate	1

COVID-19 Vaccine	Feeling Faint / Dizziness	1
COVID-19 Vaccine	Feeling Ill / Blood Pressure Spikes	1
COVID-19 Vaccine	Fever / Abdominal Pain	1
COVID-19 Vaccine	Fever / Aches	1
COVID-19 Vaccine	Fever / Arm Injury	1
COVID-19 Vaccine	Fever / Chest Pain	1
COVID-19 Vaccine	Fever / Chills / Headache / Arm Pain / weakness / Loss of Appetite	1
COVID-19 Vaccine	Fever / Chills / Nausea / Dizziness / Fatigue / Dark Stools	1
COVID-19 Vaccine	Fever / Chills / Severe Chest Pain / Shortness of Breath / Confusion	1
COVID-19 Vaccine	Fever / Chills / Shaking / Weakness	1
COVID-19 Vaccine	Fever / Chills / Shortness of Breath / Rash / Loss of Appetite / Dehydration	1
COVID-19 Vaccine	Fever / Congestion	2
COVID-19 Vaccine	Fever / Delusions / Organ Failure / Extreme Weight Loss / Inability to walk	1
COVID-19 Vaccine	Fever / Difficulty Walking	1
COVID-19 Vaccine	Fever / Headache / Body Pain / Vomiting	1
COVID-19 Vaccine	Fever / High Blood Pressure	1
COVID-19 Vaccine	Fever / Migraine / Vomiting	1
COVID-19 Vaccine	Fever / Nausea / Chills / Blood Clots Enlarged Lymph nodes	1
COVID-19 Vaccine	Fever / Nausea / Difficulty Breathing / Headache	1
COVID-19 Vaccine	Fever / Nausea / Fainted / Tiredness	1
COVID-19 Vaccine	Fever / Septic / Dehydration	1
COVID-19 Vaccine	Fever / Severe Bone and Joint Pain	1

COVID-19 Vaccine	Fever / Severe Head and Neck Pain / Body Aches / Heart Palpitations	1
COVID-19 Vaccine	Fever / Shaking / Broken Teeth	1
COVID-19 Vaccine	Fever / Swelling / Vomiting / Tonsil Edema / Dehydration / Heart Irregularities / Muscle Fatigue / Fatigue	1
COVID-19 Vaccine	Fever / Vomiting / Body Aches	1
COVID-19 Vaccine	Fever / Vomiting / Dehydration	1
COVID-19 Vaccine	Fried Shoulder and Leg Muscles / Swollen Hands / Ankle Pain	1
COVID-19 Vaccine	Flare Up of Rheumatoid Arthritis	1
COVID-19 Vaccine	Flu Like Symptoms / Dehydration	1
COVID-19 Vaccine	Frozen Shoulder	3
COVID-19 Vaccine	Frozen Shoulder / Tendinosis	1
COVID-19 Vaccine	Gastritis	1
COVID-19 Vaccine	Grand Mal Seizure	2
COVID-19 Vaccine	Guillain-Barré Syndrome (GBS)	30
COVID-19 Vaccine	Guillain-Barré Syndrome (GBS) / Death	1
COVID-19 Vaccine	Hand and Arm Numbness / Knots Under Skin / Joint Pain	1
COVID-19 Vaccine	Hand and Arm Numbness and Tingling / Rapid Heartbeat	1
COVID-19 Vaccine	Head Injury	1
COVID-19 Vaccine	Headache	1
COVID-19 Vaccine	Headache / Bilateral Neuropathy / Skin Discoloration	1
COVID-19 Vaccine	Headache / Blindness	1
COVID-19 Vaccine	Headache / Blood Pressure Drop / Dizziness	1

COVID-19 Vaccine	Headache / Fatigue / Chest Pressure	1
COVID-19 Vaccine	Headache / Leg Swelling / Pain / Blood Clots / Rare Blood Disease / Pneumonia	1
COVID-19 Vaccine	Headache / Muscle Ache / Rash / Rapid Heartbeat / Fever	1
COVID-19 Vaccine	Headache / Nausea / Diarrhea	1
COVID-19 Vaccine	Headache / Vomiting / Ketoacidosis	1
COVID-19 Vaccine	Headache / Weakness / Tinnitus	1
COVID-19 Vaccine	Headaches / Body Aches / Blood Clots	1
COVID-19 Vaccine	Headaches / Dizziness	1
COVID-19 Vaccine	Headaches / Extreme Leg Weakness	1
COVID-19 Vaccine	Headaches / Fatigue	1
COVID-19 Vaccine	Headaches / Muscle Cramps	1
COVID-19 Vaccine	Headaches / Rash	1
COVID-19 Vaccine	Headaches / Rashes / High Blood Pressure	1
COVID-19 Vaccine	Headaches / Tinnitus / Extreme Fatigue	1
COVID-19 Vaccine	Headaches / Tinnitus / Lightheadedness / Blurred Vision / Dizziness / Weakness	1
COVID-19 Vaccine	Hearing Loss	13
COVID-19 Vaccine	Hearing Loss / High Blood Pressure	1
COVID-19 Vaccine	Hearing Loss / Vocal Cord Paralysis / Fatigue / Neck Pain / Numbness / Head Pressure	1
COVID-19 Vaccine	Heart Attack	6
COVID-19 Vaccine	Heart Attack / Death	1
COVID-19 Vaccine	Heart Failure	1
COVID-19 Vaccine	Heart Failure / Atrial	1

	Fibrillation	
COVID-19 Vaccine	Heart Failure / Renal Failure	1
COVID-19 Vaccine	Heart Fibrillation	1
COVID-19 Vaccine	Heart Inflammation	1
COVID-19 Vaccine	Heart Issues / Stroke	1
COVID-19 Vaccine	Heart Palpitations	3
COVID-19 Vaccine	Heart Palpitations / Heartburn / Buzzing / Chest Pain	1
COVID-19 Vaccine	Heart Palpitations / Light Headedness	1
COVID-19 Vaccine	Heart Palpitations / Shaking / Shortness of Breath	1
COVID-19 Vaccine	Heart Racing / Palpitations / Fluttering	1
COVID-19 Vaccine	Heavy Vaginal Bleeding	1
COVID-19 Vaccine	Hemorrhagic Stroke	1
COVID-19 Vaccine	Herpes Zoster / Supraclavicular Lymphadenopathy	1
COVID-19 Vaccine	Herpes Zoster / Transverse Myelitis	1
COVID-19 Vaccine	Hidradenitis Suppurativa	1
COVID-19 Vaccine	High Blood pressure	3
COVID-19 Vaccine	High Blood Pressure / Chest Tightness / Headaches / Inability to Focus	1
COVID-19 Vaccine	High Blood Pressure / Chronic Headaches / Vertigo / Chest Pains / Ear Pain and Pressure / Eye pain / Changes in Vision	1
COVID-19 Vaccine	High Blood Pressure / Dizziness / Difficulty Breathing	1
COVID-19 Vaccine	High Blood Pressure / Facial Swelling and Numbness	1
COVID-19 Vaccine	High Blood Pressure / Fever / Seizure / Short	1

	Term Memory Loss / Numbness and Aches	
COVID-19 Vaccine	High Blood Pressure / Pain Neck, Chest, Back and Arm	1
COVID-19 Vaccine	High Blood Pressure / Severe Dizziness	1
COVID-19 Vaccine	High Blood Pressure / Tachycardia / Shortness of Breathe / Severe Headache	1
COVID-19 Vaccine	High Heart Rate / Brain Fog / Chronic Fatigue	1
COVID-19 Vaccine	High Pitched Sound in Ears / Insomnia	1
COVID-19 Vaccine	Hives	2
COVID-19 Vaccine	Hives / Difficulty Breathing	1
COVID-19 Vaccine	Hives / Fatigue / Headache / Tremors / Weakness	1
COVID-19 Vaccine	Hives / Fatigue / Vomiting / Tremors	1
COVID-19 Vaccine	Hives / Headache Swelling / Dizziness	1
COVID-19 Vaccine	Hives / Skin Discoloration	1
COVID-19 Vaccine	Hives / Urticaria / Angioedema	1
COVID-19 Vaccine	Hypertension	1
COVID-19 Vaccine	Hypertension / Tachycardia	1
COVID-19 Vaccine	Hypoglossal Nerve Palsy	1
COVID-19 Vaccine	Hypotension	1
COVID-19 Vaccine	Idiopathic Intracranial Hypertension / Esotropia	1
COVID-19 Vaccine	Idiopathic/Immune Thrombocytopenia Purpura (ITP)	8
COVID-19 Vaccine	Inability to Stand / Walk / Do Daily Routines	1
COVID-19 Vaccine	Increased Heart Rate / Convulsions / Severe Headache / Unable to Walk or Stand / Light Sensitivity	1
COVID-19 Vaccine	Infectious Cellulitis	1
COVID-19 Vaccine	Inflamed Lymph Nodes	1

COVID-19 Vaccine	Inflamed Rotator Cuff	1
COVID-19 Vaccine	Inflammation / High Blood Pressure and Heart Rate / Rash / Hives / Trouble Breathing	1
COVID-19 Vaccine	Inflammation / Swelling / Extreme Pain	1
COVID-19 Vaccine	Inflammation in Hands and Wrists	1
COVID-19 Vaccine	Inflammatory Arthritis	1
COVID-19 Vaccine	Inflammatory Myelitis	1
COVID-19 Vaccine	Insomnia	1
COVID-19 Vaccine	Intense Chest Pains	1
COVID-19 Vaccine	Internal Bleeding / Mouth Blisters	1
COVID-19 Vaccine	Interstitial Lung Disease / Chronic Respiratory Failure	1
COVID-19 Vaccine	Irregular Heart Beat / Heart Failure	1
COVID-19 Vaccine	Irregular Heart Rhythm / Tachycardia / Severe Chest Pain / Left Side Numbness	1
COVID-19 Vaccine	Ischemic Colitis	2
COVID-19 Vaccine	Ischemic Stroke	3
COVID-19 Vaccine	Itching / Rash / Nausea / Vomiting	1
COVID-19 Vaccine	ITP / Chronic Bleeding Disorder	1
COVID-19 Vaccine	Jaundice / Lethargy / Loss of Appetite	1
COVID-19 Vaccine	Jaw, Chest and Neck Pain / Chest Pressure / Shortness of Breath / Extreme Nausea	1
COVID-19 Vaccine	Joint Inflammation	1
COVID-19 Vaccine	Joint Inflammation / Joint Pain	1
COVID-19 Vaccine	Joint Pain and Swelling	1
COVID-19 Vaccine	Kidney Injury / Arm Injury	1
COVID-19 Vaccine	Kidney Stones	1
COVID-19 Vaccine	Left / Right Leg Numbness	1

COVID-19 Vaccine	Left Arm and Hand Numbness	1
COVID-19 Vaccine	Left Perilymphatic Fistula / Right Perilymphatic Fistula / Elevated Intracranial Pressure / Bilateral Eustachian Tube Dysfunction	1
COVID-19 Vaccine	Left Side Numbness / Back Pain / Ear Pain / Drooling / Brain Fog	1
COVID-19 Vaccine	Left Side Numbness / Fainted	1
COVID-19 Vaccine	Left Side Numbness / Knee and Leg Pain	1
COVID-19 Vaccine	Left Side Paralysis	1
COVID-19 Vaccine	Left Side Weakness	1
COVID-19 Vaccine	Left Side Weakness / Difficulty Breathing / Migraine / Heart Palpitations / Wheezing / Dizziness / Joint Pain	1
COVID-19 Vaccine	Leg Pain	1
COVID-19 Vaccine	Leg Pain / Chest Pain	1
COVID-19 Vaccine	Lesions	1
COVID-19 Vaccine	Leukoycto Clastic Vasculitis with Dermal Neutrophil	1
COVID-19 Vaccine	Lichen Planus	1
COVID-19 Vaccine	Light Headedness / Extreme Fatigue / Faintness	1
COVID-19 Vaccine	Lightheaded / Cold Sweat / Chills	1
COVID-19 Vaccine	Lightheaded / Dizziness / Nausea	1
COVID-19 Vaccine	Lightheaded / Throat Swelling / Difficulty Breathing	1
COVID-19 Vaccine	Lipoma of Subcutaneous Tissue (Left Arm)	1
COVID-19 Vaccine	Liver Damage	1
COVID-19 Vaccine	Liver Injury	1
COVID-19 Vaccine	LLE / LUE Weakness / Facial Numbness /	1

	Difficulty Speaking	
COVID-19 Vaccine	Loss of Body Functions	1
COVID-19 Vaccine	Loss of Eye Sight	1
COVID-19 Vaccine	Loss of Sensation in Extremities / Tinnitus / Headache	1
COVID-19 Vaccine	Lost Consciousness	1
COVID-19 Vaccine	Low Blood Pressure / Chest Pain	1
COVID-19 Vaccine	Low Blood Pressure / Difficulty Breathing	1
COVID-19 Vaccine	Low Blood Pressure / Fluid In Lungs / Pancreatitis	1
COVID-19 Vaccine	Low Blood Sugar / Low Blood Pressure / Low Energy / Pneumonia	1
COVID-19 Vaccine	Low Hemoglobin	1
COVID-19 Vaccine	Low O2 Saturation	1
COVID-19 Vaccine	Low Oxygen / Fatigue	1
COVID-19 Vaccine	Low Platelet Count	1
COVID-19 Vaccine	Lung Infection	1
COVID-19 Vaccine	Lung Nodules / Migraine	1
COVID-19 Vaccine	Lymph Node Mass	1
COVID-19 Vaccine	Memory Loss / Hallucinating	1
COVID-19 Vaccine	Meningitis / Syringomyelia	1
COVID-19 Vaccine	Mesenteric Venous Thrombosis	1
COVID-19 Vaccine	Migraine / Chronic Fatigue	1
COVID-19 Vaccine	Mesenteric Venous Thrombosis / Septic Thrombophlebitis	1
COVID-19 Vaccine	Migraine / Joint Pain / Fatigue	1
COVID-19 Vaccine	Migraine Headache	2
COVID-19 Vaccine	Migraine Headaches / High Blood Pressure	1
COVID-19 Vaccine	Mild Heart Attack	1
COVID-19 Vaccine	Miscarriage	1

COVID-19 Vaccine	Multisystem Inflammatory Syndrome	1
COVID-19 Vaccine	Muscle Aches / Swelling / Cough / Chills / Night Sweats / Dizziness / Elevated WBC / Stomach Ache / Fatigue / Difficulty Ambulating	1
COVID-19 Vaccine	Muscle Pain / Body Aches	1
COVID-19 Vaccine	Muscle Spasms / Breathing Abnormality / Pain	1
COVID-19 Vaccine	Myasthenia Gravis Disease	2
COVID-19 Vaccine	Myocarditis	19
COVID-19 Vaccine	Myocarditis / Heart Attack	1
COVID-19 Vaccine	Myocarditis / Pericarditis	5
COVID-19 Vaccine	Myocarditis / Pneumonia	1
COVID-19 Vaccine	Myoclonus Seizures / Uncontrollable Laughter / Fatigue / Headaches / Loss of Taste, Appetite, Weight / High Blood Pressure / Tinnitus / Ingrown Nails / Blurry Vision / Constipation / Dehydration / Confusion / Numbness	1
COVID-19 Vaccine	Myopericarditis	5
COVID-19 Vaccine	Nausea / Chest Pains / Migraines / Numbness	1
COVID-19 Vaccine	Nausea / Diarrhea / Headache / Sweating	1
COVID-19 Vaccine	Nausea / Dizziness / Difficulty Breathing / Fever / Sweating	1
COVID-19 Vaccine	Nausea / Facial Pain / Trouble Thinking / Pain in Shoulders and Knees / Heart Fluttering	1
COVID-19 Vaccine	Nausea / Fatigue / Tongue Swelling / Neck and Shoulder Pain	1
COVID-19 Vaccine	Nausea / Fever / Shortness of Breath	1
COVID-19 Vaccine	Nausea / Hives / Shaking	1
COVID-19 Vaccine	Nausea / Right Limb Weakness / Vomiting / Memory Loss / Confusion	1

COVID-19 Vaccine	Nausea / Vomiting / Diarrhea / Leg and Knee Pain / Encephalopathy	1
COVID-19 Vaccine	Nausea / Vomiting / Diarrhea / Loss of Appetite / Weight Loss / Malnutrition	1
COVID-19 Vaccine	Nausea / Vomiting / Headache / Difficulty Breathing	1
COVID-19 Vaccine	Nausea / Vomiting / Lethargy	1
COVID-19 Vaccine	Nerve Damage	1
COVID-19 Vaccine	Nerve Damage / Muscle Atrophy	1
COVID-19 Vaccine	Nerve Pain / Vision Weakness / Muscle Fatigue / Headache	1
COVID-19 Vaccine	Neurologic / Cardiovascular / Gynecologic Issues	1
COVID-19 Vaccine	Neurologic Disorder	1
COVID-19 Vaccine	Neurologic Symptoms	2
COVID-19 Vaccine	Neurological Damage	1
COVID-19 Vaccine	Neurological Reaction / Paresthesia	1
COVID-19 Vaccine	Neuropathy / Joint Pain / Palpitations	1
COVID-19 Vaccine	Night Sweats / Fatigue / Nausea / Vomiting / Diarrhea	1
COVID-19 Vaccine	Non-specific Paresthesia	1
COVID-19 Vaccine	Not Specified	58
COVID-19 Vaccine	Numbness	2
COVID-19 Vaccine	Numbness / Bruising / Pain	1
COVID-19 Vaccine	Numbness / Pain / Tingling / Inability to Stand or Walk	1
COVID-19 Vaccine	Numbness / Swelling / Chest Pain	1
COVID-19 Vaccine	Numbness / Weakness in Legs	1
COVID-19 Vaccine	Numbness and Bruising	1

COVID-19 Vaccine	Numbness in Feet	1
COVID-19 Vaccine	Numbness on Entire Left Side	1
COVID-19 Vaccine	Open Wound / Hand & Foot / COVID Pneumonia / Enlarged Lymph Nodes	1
COVID-19 Vaccine	Optic Migraine	1
COVID-19 Vaccine	Pain / Headache / Facial Distortion	1
COVID-19 Vaccine	Pain / Mouth Infection	1
COVID-19 Vaccine	Pain / Nausea / Dizziness / Fainting	1
COVID-19 Vaccine	Pain / Numbness / Weakness in Arm	1
COVID-19 Vaccine	Pain / Skin Lesions	1
COVID-19 Vaccine	Pain in Shins and Ankles	1
COVID-19 Vaccine	Pain Throughout Body	1
COVID-19 Vaccine	Pancolitis / C. Diff. Infection	1
COVID-19 Vaccine	Pancreatitis	1
COVID-19 Vaccine	Pancytopenia	1
COVID-19 Vaccine	Paralysis	6
COVID-19 Vaccine	Paralysis / Pain / Headaches	1
COVID-19 Vaccine	Paralyzed Vocal Cord	1
COVID-19 Vaccine	Paresthesia	3
COVID-19 Vaccine	Paresthesia / Nerve Pain / Muscle and Joint Pain / Weakness / Tongue Tingling / Eye Irritation	1
COVID-19 Vaccine	Parsonage Turner Syndrome (PTS)	3
COVID-19 Vaccine	Passed Out	1
COVID-19 Vaccine	Pericardial Enhancement	1
COVID-19 Vaccine	Pericarditis	17
COVID-19 Vaccine	Pericardium Cyst	1
COVID-19 Vaccine	Peripheral Neuropathy	1
COVID-19 Vaccine	Petchiae / Low Platelets / Splenectomy	1

COVID-19 Vaccine	Petechiae	1
COVID-19 Vaccine	Petechiae / Bleeding	1
COVID-19 Vaccine	Petechiae / Headache / Nausea	1
COVID-19 Vaccine	Phantosmia	1
COVID-19 Vaccine	Pneumonia	1
COVID-19 Vaccine	Pneumonia / Bronchitis	1
COVID-19 Vaccine	Pneumonia / Decreased Potassium	1
COVID-19 Vaccine	Poisoning by Vaccine and Biological Substances	1
COVID-19 Vaccine	Polymyalgia Rheumatica	1
COVID-19 Vaccine	Polymyositis	1
COVID-19 Vaccine	Polyneuropathy / Critical Illness Myopathy	1
COVID-19 Vaccine	Post Stroke Recudence	1
COVID-19 Vaccine	Posterior Leukoencephalopathy	1
COVID-19 Vaccine	Postural Orthostatic Tachycardia Syndrome (POTS)	2
COVID-19 Vaccine	Pressure in Head and Neck / Chest Pain / Blood Clots	1
COVID-19 Vaccine	Primary Sclerosing Cholangitis	1
COVID-19 Vaccine	Psoriasis / Moderate Osteoarthritis	1
COVID-19 Vaccine	Psoriasis / Onycholysis / Edema / Xerosis	1
COVID-19 Vaccine	Psychosis	1
COVID-19 Vaccine	Ptosis / Palsy	2
COVID-19 Vaccine	Pulmonary Embolism	19
COVID-19 Vaccine	Pulmonary Embolism / Blood Clots / Heart Strain	1
COVID-19 Vaccine	Pulmonary Embolism / Hypothyroidism / Generalized Joint Pain	1
COVID-19 Vaccine	Pulmonary Embolism / Lung Infarction / Hypercoagulability	1

COVID-19 Vaccine	Queasy Feeling	1
COVID-19 Vaccine	Quincke Edema / Injection Site Injury / Fever / Swelling	1
COVID-19 Vaccine	Radial Artery Thrombus / Angina	1
COVID-19 Vaccine	Rapid Heart Rate	1
COVID-19 Vaccine	Rapid Heart Rate / Difficulty Breathing	1
COVID-19 Vaccine	Rapid Heartbeat	4
COVID-19 Vaccine	Rash	15
COVID-19 Vaccine	Rash / Allergic Reaction	1
COVID-19 Vaccine	Rash / Elevated Heart Rate / Chest Pain / Dizziness	1
COVID-19 Vaccine	Rash / Hives	1
COVID-19 Vaccine	Rash / Nerve Pain	1
COVID-19 Vaccine	Rash / Shortness of Breath / Rapid Heartbeat / Dizziness / Fainted / Joint Pain / Headache	1
COVID-19 Vaccine	Rash / Swelling	2
COVID-19 Vaccine	Rashes	1
COVID-19 Vaccine	Recurring Epistaxis	1
COVID-19 Vaccine	Respiratory Failure / Influenza A / Necrotizing Pneumonia / Acute Kidney Injury	1
COVID-19 Vaccine	Rhabdomyolysis / Dizziness / Chest Pain / Right Bundled Branch Block	1
COVID-19 Vaccine	Rheumatoid Arthritis	1
COVID-19 Vaccine	Right Dural Venus Thrombosis	1
COVID-19 Vaccine	Right Side Numbness / Loss of Voice / Bowel Movement Issues	1
COVID-19 Vaccine	Right Side Numbness / Nausea / Dizziness	1
COVID-19 Vaccine	Right Side Paralysis	1
COVID-19 Vaccine	Robust Reactions	1

COVID-19 Vaccine	Rotator Cuff Tear	1
COVID-19 Vaccine	Rotator Cuff Tear / Advanced Tendinopathy / Left Shoulder Capsulitis	1
COVID-19 Vaccine	Ruptured Tendon	1
COVID-19 Vaccine	Seizure / Dysphagia	1
COVID-19 Vaccine	Seizures	11
COVID-19 Vaccine	Sepsis	1
COVID-19 Vaccine	Severe Abdominal Pain	1
COVID-19 Vaccine	Severe Allergic Reaction	14
COVID-19 Vaccine	Severe Anaphylaxis	1
COVID-19 Vaccine	Severe Aplastic Anemia	1
COVID-19 Vaccine	Severe Arm Pain	1
COVID-19 Vaccine	Severe Arm Pain / Fainting	1
COVID-19 Vaccine	Severe Arm Pain / Rapid Heartbeat	1
COVID-19 Vaccine	Severe Back, Neck and Head Pain	1
COVID-19 Vaccine	Severe Bruising / Arm Pain	1
COVID-19 Vaccine	Severe Chest and Abdominal Pain	1
COVID-19 Vaccine	Severe Chest and Head Pain	1
COVID-19 Vaccine	Severe Chest Pain	1
COVID-19 Vaccine	Severe Chest Pain / Shortness of Breath / Migraine like Pain / Seizure / Dizziness / Light Sensitivity / Dry Mouth / Hoarse Throat / Tingling / Numbness	1
COVID-19 Vaccine	Severe Chills / Pain / Fever / Vomiting / Fainted	1
COVID-19 Vaccine	Severe Chronic Pain	1
COVID-19 Vaccine	Severe Fatigue / Fever / Chills / Pain	1
COVID-19 Vaccine	Severe Flu Like Symptoms	1
COVID-19 Vaccine	Severe Groin, Knee, Elbow and Hand Pain	1
COVID-19 Vaccine	Severe Headache / Body	1

	Aches / Difficulty Concentrating / Photo Sensitivity	
COVID-19 Vaccine	Severe Headache / Chills / Nausea / Vomiting / Fatigue	1
COVID-19 Vaccine	Severe Headache / Elevated Blood Pressure and Pulse / Abdominal Pain	1
COVID-19 Vaccine	Severe Headaches / Tingling / Numbness	1
COVID-19 Vaccine	Severe Itching / Allergic Reaction	1
COVID-19 Vaccine	Severe Itching / Blisters	1
COVID-19 Vaccine	Severe Joint Pain / Fever / Asthma	1
COVID-19 Vaccine	Severe Leg and Back Pain / Extreme Fatigue	1
COVID-19 Vaccine	Severe Leg Pain	1
COVID-19 Vaccine	Severe Lower Back Pain / Dizziness / Headaches	1
COVID-19 Vaccine	Severe Migraines / Pain / Fatigue	1
COVID-19 Vaccine	Severe Muscle Pain / Internal Bleeding	1
COVID-19 Vaccine	Severe Nausea / Dizziness / Dehydration	1
COVID-19 Vaccine	Severe Pain and Fatigue	1
COVID-19 Vaccine	Severe Pain and Weakness in Shoulder and Arm	1
COVID-19 Vaccine	Severe Rash / Hives	1
COVID-19 Vaccine	Severe Rashes	1
COVID-19 Vaccine	Severe Reaction / Low Heart Rate	1
COVID-19 Vaccine	Severe Tinnitus / Dizziness	1
COVID-19 Vaccine	Severe Vaginal Bleeding	1
COVID-19 Vaccine	Severe Vasculitis	1
COVID-19 Vaccine	Severe Vertigo / Leg Cramps / Exhaustion / Night Sweats / Headaches	1
COVID-19 Vaccine	Shaking / Muscle	1

	Weakness / Nerve Pain / GBS like symptoms	
COVID-19 Vaccine	Shaking / Numbness / Swelling / Severe Chest Pressure and Pressure / Sweating	1
COVID-19 Vaccine	Shaking / Swelling / Headaches	1
COVID-19 Vaccine	Shingles	6
COVID-19 Vaccine	Shingles / COVID-19	1
COVID-19 Vaccine	Shocking Sensation in Arteries or Veins / Fatigue / Flu Like Symptoms / Pain in Stomach and Legs	1
COVID-19 Vaccine	Shortness of Breath / Arm Injury	1
COVID-19 Vaccine	Shortness of Breath / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Chest Pains / Extreme Swelling	1
COVID-19 Vaccine	Shortness of Breath / Chest Pressure / Tingling in Hands and Feet	1
COVID-19 Vaccine	Shortness of Breath / Confusion / Severe Headache	1
COVID-19 Vaccine	Shortness of Breath / Fast Heartbeat / Panic Attack / Shoulder Pain / Anxiety / Frozen Extremities / Dizziness	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / COVID Pneumonia	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / Fever/ Headache / Body Ache	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / Heavy Limbs	1
COVID-19 Vaccine	Shortness of Breath / Fever / Chills / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Racing Heartbeat	1
COVID-19 Vaccine	Shortness of Breath / Rapid Heartbeat / Dizziness	1

COVID-19 Vaccine	Shortness of Breath / Rash / Migraine	1
COVID-19 Vaccine	Shortness of Breath / Shivering / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Sore Muscles / Chest Pains / Flu Like Symptoms	1
COVID-19 Vaccine	Shortness of Breath / Swelling / High Blood Pressure / Heart Problems / Anxiety	1
COVID-19 Vaccine	Shortness of Breath / Wheezing / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Heart Palpitations/ Leg Pain / Dizziness	1
COVID-19 Vaccine	Shoulder / Arm Injury	9
COVID-19 Vaccine	Shoulder Injury	25
COVID-19 Vaccine	Shoulder Pain	8
COVID-19 Vaccine	Sinusitis	1
COVID-19 Vaccine	SIRVA	7
COVID-19 Vaccine	Sixth Nerve Palsy	1
COVID-19 Vaccine	Skin and Gum Sensitivity / Anal Fistulas	1
COVID-19 Vaccine	Skin Rash / Muscle Weakness	1
COVID-19 Vaccine	Slurred Speech / Face Drooping / Tingling in Face	1
COVID-19 Vaccine	Small Fiber Neuropathy	2
COVID-19 Vaccine	Spasms / Cramps / Swollen Tongue / Shingles	1
COVID-19 Vaccine	Spinal Meningitis	1
COVID-19 Vaccine	Spongiotic Dermatitis	1
COVID-19 Vaccine	Stevens Johnson Syndrome	1
COVID-19 Vaccine	Stiff Neck / Migraine	1
COVID-19 Vaccine	Stroke	28
COVID-19 Vaccine	Stroke / Blood Clots	1
COVID-19 Vaccine	Stroke / Death	1
COVID-19 Vaccine	Stroke Like Symptoms	3

COVID-19 Vaccine	Stroke Like Symptoms / Collapsed Lung	1
COVID-19 Vaccine	Subacromial Bursitis	1
COVID-19 Vaccine	Subarachnoid Hemorrhage / Seizure / Traumatic Brain Injury	1
COVID-19 Vaccine	Subcutaneous Sarcoidosis	1
COVID-19 Vaccine	Sudden Hearing Loss (SSHL) / Sudden Deafness	1
COVID-19 Vaccine	Sulphur Taste and Smell	1
COVID-19 Vaccine	Supraventricular Tachycardia	2
COVID-19 Vaccine	Swelling	1
COVID-19 Vaccine	Swelling / Burning / Inflammation	1
COVID-19 Vaccine	Swelling / Headaches / Bad Dreams / Drowsiness / Stroke / Low Blood Pressure	1
COVID-19 Vaccine	Swelling / Hives	1
COVID-19 Vaccine	Swelling / Rash / Skin Peeling	1
COVID-19 Vaccine	Swelling / Trouble Breathing	1
COVID-19 Vaccine	Swollen and Inflamed Lymph Nodes / Cystic Nodule	1
COVID-19 Vaccine	Swollen Ankle	1
COVID-19 Vaccine	Swollen Feet, Arms and Tongue	1
COVID-19 Vaccine	Swollen Finger	1
COVID-19 Vaccine	Swollen Hands / Tingling / Nerve Pain / Eczema	1
COVID-19 Vaccine	Swollen Lymph Nodes	4
COVID-19 Vaccine	Swollen Lymph Nodes / Asthma	1
COVID-19 Vaccine	Syncope	4
COVID-19 Vaccine	Syncope / Concussion / Cheek Bone & Teeth Fractures	1
COVID-19 Vaccine	Syncope / Confusion / Headaches	1

COVID-19 Vaccine	Syncope / Face Head and Nose Injury	1
COVID-19 Vaccine	Syncope / Hypertension / Ischemic Tachycardia / Non-Ischemic Cardiomyopathy / Non-sustained Ventricular Tachycardia / Atrial Fibrillation / Pulmonary Interstitial Edema	1
COVID-19 Vaccine	Systemic Inflammatory Response Syndrome (SIRS)	2
COVID-19 Vaccine	Tachycardia	5
COVID-19 Vaccine	Tachycardia / Diaphoretic	1
COVID-19 Vaccine	Tachycardia / Hypertension / Palpitation	1
COVID-19 Vaccine	Tachycardia / Shortness of Breath / Tremors / Hot Flashes / Paresthesia / Blurred Vision / Near Syncope / Muscle Tension	1
COVID-19 Vaccine	Throat Inflammation / Muscle Pain / Fever	1
COVID-19 Vaccine	Throat Swelling	1
COVID-19 Vaccine	Throat Swelling / Itching / Redness / Heavy Menstrual Flow / Headache / Fatigue / Numbness / Arm Pain	1
COVID-19 Vaccine	Throat Swelling / Tachycardia / Heart Palpitations	1
COVID-19 Vaccine	Throat Tongue Hand and Arm Swelling / Lesions	1
COVID-19 Vaccine	Thrombocytopenia	3
COVID-19 Vaccine	Thrombocytopenia / Cellulitis	1
COVID-19 Vaccine	Thrombosis	2
COVID-19 Vaccine	Thrush / Swollen Tongue, Plate and Gums	1
COVID-19 Vaccine	Thrush / Symptoms of Systemic Inflammatory Response Syndrome	1
COVID-19 Vaccine	Thyroid Storm	1
COVID-19 Vaccine	TIA Stroke	2

COVID-19 Vaccine	Tingling / Numbness / Paralysis	1
COVID-19 Vaccine	Tingling / Rash / Rapid Heartbeat	1
COVID-19 Vaccine	Tinnitus	9
COVID-19 Vaccine	Tinnitus / Hearing Loss	2
COVID-19 Vaccine	Tinnitus / Vertigo / Vomiting	1
COVID-19 Vaccine	Tonsillitis	1
COVID-19 Vaccine	Transient Global Amnesia	1
COVID-19 Vaccine	Transverse Myelitis	8
COVID-19 Vaccine	Transverse Myelitis / GBS	1
COVID-19 Vaccine	Trigger Finger	1
COVID-19 Vaccine	TTS	1
COVID-19 Vaccine	Ulcerative Colitis	1
COVID-19 Vaccine	Unable to Breathe / Unresponsive	1
COVID-19 Vaccine	Unable to Walk	1
COVID-19 Vaccine	Unresponsive / Foaming at Mouth / Low Blood Pressure	1
COVID-19 Vaccine	Unresponsive / Tachycardia / Low Heart Rate / Pain	1
COVID-19 Vaccine	UTI	1
COVID-19 Vaccine	Vaccine Induced Axillary Lymphadenopathy	1
COVID-19 Vaccine	Vasculitis	1
COVID-19 Vaccine	Vasculitis / Trouble Swallowing Food / Weakness	1
COVID-19 Vaccine	Vasovagal Syncope	4
COVID-19 Vaccine	Vertigo / Brain Fog	1
COVID-19 Vaccine	Vertigo / Dizziness / Lightheadedness / Low Energy	1
COVID-19 Vaccine	Vertigo / Migraine	1
COVID-19 Vaccine	Vertigo / Vomiting	1
COVID-19 Vaccine	Vestibular Neuritis	4

COVID-19 Vaccine	Vestibular Neuritis / Migraines / Severe Inflammation	1
COVID-19 Vaccine	Vestibular Neuritis / Tinnitus	1
COVID-19 Vaccine	Vision Loss	5
COVID-19 Vaccine	Vision Loss / Fainted	1
COVID-19 Vaccine	Vision Loss / Muscle Spasms / High Blood Pressure	1
COVID-19 Vaccine	Vision Loss/ Balance Issues / Headaches / Fatigue / Vertigo / Chest Tightness	1
COVID-19 Vaccine	Vocal Cord Dysfunction	1
COVID-19 Vaccine	Vomiting / Fever / Dehydration / Rapid Heartbeat	1
COVID-19 Vaccine	Vomiting / Shortness of Breath	1
COVID-19 Vaccine	Vomiting / Shortness of Breath / Tachycardia	1
COVID-19 Vaccine	VTE / DVT	1
COVID-19 Vaccine	Weakness / Breathing Difficulty / Difficulty Swallowing and Chewing / Double Vision	1
COVID-19 Vaccine	Weakness / Difficulty Walking	2
COVID-19 Vaccine	Weakness / Difficulty Walking / Extreme Body Aches	1
COVID-19 Vaccine	Weakness / Fatigue / Fever / Muscle Pain / Headaches / Chills / Cold Sweats / Cognitive Issues / Chest Tightness / Shortness of Breath / Numbness	1
COVID-19 Vaccine	Weakness / Fatigue / Heart and Blood Pressure Issues	1
COVID-19 Vaccine	Wheezing / Coughing / Shortness of Breath / Blurred Vision	1
COVID-19 Vaccine	Wheezing / Lightheadedness / Dizziness / Metal Taste in Mouth	1

COVID-19 Vaccine	Wheezing / Muscle Weakness / Migraine / Hypertension	1
COVID-19 Vaccine / Remdesivir	Death	1
Decadron / Remdesivir	Death	1
Delay or Failure to Provide Proper Medication and Treatment	Death	1
Dexamethasone	Death	1
Dexamethasone / Doxycycline / Piperacillin-Tazobactam	Death	1
Dexamethasone / Remdesivir	Death	1
Extracorporeal Membrane Oxygenation Machine	Death	1
Failure to Abide by COVID-19 Regulations	Death	1
Hydroxychloroquine	Death	18
Hydroxychloroquine / Azithromycin	Death	1
Hydroxychloroquine / Dexamethasone / Dialysis	Death	1
Hydroxychloroquine / Fentanyl / Intubation	Death	1
Hydroxychloroquine / Medrol	Death	1
Hydroxychloroquine / Odansetron	Death	1
Hydroxychloroquine / Remdesivir	Death	5
Hydroxychloroquine / Remdesivir / Convalescent Plasma	Death	1
Hydroxychloroquine / Sarilumab	Death	1
Hydroxychloroquine / Solu-Medrol / Tocilizumab	Death	2
Intubation	Death	4
Mefloquine	Dizziness / Hearing Loss / PTSD / Tinnitus / Temperature Sensitivity	1
N-95 Mask	Shoulder Injury	1
N-95 Mask / PPE	COVID	1
N-95 Mask / Ventilator	Death	1
Not Specified	Bell's Palsy	1
Not Specified	Death	133
Not Specified	DVT / Chest Pain / Neurologic Symptoms	1
Not Specified	Not Specified	3
Not Specified	Pancreatitis	1
Not Specified	TIA Stroke	1

Not Specified	Ulcer / Myopathy	1
Not Specified	Weakness / Difficulty Walking	1
Oxygen / Prednisone	Death	1
Oxygen / Remdesivir	Death	1
Permavir / Remdesivir / Steroids	Death	1
Remdesivir	Death	29
Remdesivir	Renal Failure / Pulmonary Embolism / Pneumonia	1
Remdesivir / Tocilizumab	Death	1
Stay At Home Order / Masks / No Elective Surgeries	Attempted Murder / Assault / Damage to Multiple Body Parts	1
Tylenol	Death	1
Ventilator	Collapsed Lung	1
Ventilator	Death	138
Ventilator / Acute Blood Loss / Blood Transfusion	Death	1
Ventilator / Anakinra / Ceftriaxone / Convalescent Plasma / Heparin / Medrol / Steroids / Tocilizumab	Death	1
Ventilator / Antibiotics / Intubation / Sedation	Death	1
Ventilator / Antiviral Medications	Death	2
Ventilator / Antivirals / Convalescent Plasma / Neglect / Pneumonia	Death	1
Ventilator / Azithromycin	Death	10
Ventilator / Azithromycin	Respiratory Failure / Kidney Failure	1
Ventilator / Azithromycin / BiPap / Dialysis / Plaquenil / Tocilizumab	Death	2
Ventilator / Azithromycin / BiPap / Remdesivir	Death	1
Ventilator / Azithromycin / Ceftriaxone	Death	1
Ventilator / Azithromycin / Ceftriaxone / Dialysis / Heparin / Steroids	Death	1
Ventilator / Azithromycin / Ceftriaxone / Dialysis / Heparin / Vancomycin	Death	1
Ventilator / Azithromycin / Convalescent Plasma	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Decadron / Dialysis	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Medrol / Remdesivir	Death	2
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir / Tocilizumab	Death	2

Ventilator / Azithromycin / Convalescent Plasma / Dialysis / Remdesivir / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir	Death	3
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir / Steroids	Death	2
Ventilator / Azithromycin / Convalescent Plasma / Steroids	Death	1
Ventilator / Azithromycin / Decadron / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Azithromycin / Dexamethasone	Death	4
Ventilator / Azithromycin / Dexamethasone / Dialysis	Death	1
Ventilator / Azithromycin / Dexamethasone / Dialysis / Solumedrol	Death	1
Ventilator / Azithromycin / Dexamethasone / Medrol / Remdesivir	Death	1
Ventilator / Azithromycin / Dexamethasone / Methylprednisolone / Remdesivir	Death	2
Ventilator / Azithromycin / Dexamethasone / Remdesivir	Death	6
Ventilator / Azithromycin / Dexamethasone / Remdesivir / Steroids	Death	1
Ventilator / Azithromycin / Dialysis / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Heparin	Death	1
Ventilator / Azithromycin / Ivermectin / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Ivermectin / Remdesivir	Death	1
Ventilator / Azithromycin / Methylprednisolone	Death	1
Ventilator / Azithromycin / Remdesivir	Death	7
Ventilator / Azithromycin / Sedation	Death	1
Ventilator / Azithromycin / Tocilizumab	Death	1
Ventilator / BiPap	Death	2
Ventilator / BiPAP / COVID-19 Medications	Death	1
Ventilator / BiPAP / COVID-19 Medications / Oxygen	Death	1
Ventilator / BiPap / Remdesivir	Death	4
Ventilator / BiPap / Soliris / Remdesivir	Death	1
Ventilator / Ceftriaxone / Remdesivir	Death	1
Ventilator / Convalescent Plasma	Death	6
Ventilator / Convalescent Plasma / Covid-19 Medications	Death	1

Ventilator / Convalescent Plasma / Decadron / Intubation / Lorazepam	Death	1
Ventilator / Convalescent Plasma / Dexamethasone / Remdesivir	Death	1
Ventilator / Convalescent Plasma / Dialysis	Death	1
Ventilator / Convalescent Plasma / Intubation	Death	1
Ventilator / Convalescent Plasma / Remdesivir	Death	6
Ventilator / Convalescent Plasma / Remdesivir / Tocilizumab	Death	1
Ventilator / Covid-19 Medications	Death	666
Ventilator / COVID-19 Medications / COVID-19 Test	Death	1
Ventilator / COVID-19 Medications / Oxygen	Death	1
Ventilator / COVID-19 Vaccine	Death	6
Ventilator / CPAP	Death	1
Ventilator / Dexamethasone	Death	1
Ventilator / Dexamethasone / Dialysis	Death	1
Ventilator / Dexamethasone / Dialysis / Methylprednisolone / Remdesivir	Death	1
Ventilator / Dexamethasone / Remdesivir	Death	3
Ventilator / Dexamethasone / Remdesivir / Tocilizumab	Death	1
Ventilator / Dialysis	Death	1
Ventilator / Endotracheal Tube	Death	1
Ventilator / Hydroxychloroquine	Death	20
Ventilator / Hydroxychloroquine / Antibiotics / Intubation / PIC Line / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Antibiotics / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin	Death	49
Ventilator / Hydroxychloroquine / Azithromycin / Aztreonam / Dexamethasone / Linezolid	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / BiPap / Convalescent Plasma / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / BiPap / Dialysis / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Convalescent Plasma / Doxycycline / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Dialysis / Heparin / Tocilizumab / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Steroids	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Steroids / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Tocilizumab	Death	1

Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / CPAP / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Dialysis	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone / Dialysis / Solu-Medrol / Steroids / Tocilizumab	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis	Death	11
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Heparin / Vasopressin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Solu-Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Solu-Medrol/ Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Steroids	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Steroids / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Tocilizumab	Death	3
Ventilator / Hydroxychloroquine / Azithromycin / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Heparin / Medrol / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Medrol / Vancomycin	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone	Death	5
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone / Remdesivir / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone / Tocilizumab	Death	3
Ventilator / Hydroxychloroquine / Azithromycin / Plaquenil	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Plaquenil / Zithromax	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Remdesivir	Death	19
Ventilator / Hydroxychloroquine / Azithromycin / Remdesivir / Tocilizumab / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Solu-Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Solu-Medrol / Tocilizumab	Death	1

Ventilator / Hydroxychloroquine / Azithromycin / Steroids / Medrol / Ceftriaxone / Heparin / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Steroids / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Tocilizumab	Death	5
Ventilator / Hydroxychloroquine / Ceftriaxone / Convalescent Plasma / Heparin / Medrol / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Ceftriaxone / Heparin	Death	1
Ventilator / Hydroxychloroquine / Ceftriaxone / Heparin / Medrol / Steroids	Death	1
Ventilator / Hydroxychloroquine / Convalescent Plasma	Death	1
Ventilator / Hydroxychloroquine / Convalescent Plasma / Dialysis / Methylprednisolone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Covid-19 Test	Death	1
Ventilator / Hydroxychloroquine / Dexamethasone / Dialysis	Death	1
Ventilator / Hydroxychloroquine / Dexamethasone / Methylprednisolone / Remdesivir / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Dialysis / Heparin / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Dialysis / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Heparin / Medrol / Steroids / Vancomycin / Ventilator	Death	1
Ventilator / Hydroxychloroquine / Medrol	Death	1
Ventilator / Hydroxychloroquine / Methylprednisolone	Death	1
Ventilator / Hydroxychloroquine / Methylprednisolone / Remdesivir / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Remdesivir	Death	7
Ventilator / Hydroxychloroquine / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Steroids / Tocilizumab	Death	2
Ventilator / Hydroxychloroquine / Z-Pac	Death	1
Ventilator / Intubation	Death	3
Ventilator / Lovenox	Death	1
Ventilator / Permavir / Relenza	Death	1
Ventilator / Plaquenil	Death	1
Ventilator / Remdesivir	Death	31
Ventilator / Remdesivir / Convalescent Plasma	Death	3
Ventilator / Remdesivir / Methylprednisolone	Death	1
Ventilator / Remdesivir / Seasonal Flu Vaccine / Midazolam	Death	1
Ventilator / Remdesivir / Steroids	Death	1
Ventilator / Remdesivir / Tocilizumab	Death	1

Ventilator / Tamiflu	Not Specified	1
Ventilator / Tocilizumab	Death	1
Ventilator / Tranquilizer	Death	1
Total COVID-19		**3,158**

Table 2. CICP Claims Compensated (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure, alleged injury and amount of compensation paid for each compensated CICP claim filed between Fiscal Years 2010 through 2021.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury	Compensation Amount
1	H1N1 Vaccine	Guillain-Barrè Syndrome (GBS)	$2,309.94
2	H1N1 Vaccine	Bursitis	$385.00
3	H1N1 Vaccine	Anaphylaxis	$1,885.44
4	Smallpox Vaccine	Myocarditis	$323,035.75
5	H1N1 Vaccine	Anaphylaxis	$2,995.23
6	H1N1 Vaccine	Shoulder Pain	$182.20
7	H1N1 Vaccine	GBS	$1,762,920.56
8	H1N1 Vaccine	GBS	$185,479.52
9	H1N1 Vaccine	GBS	$15,662.07
10	H1N1 Vaccine	GBS	$106,723.54
11	H1N1 Vaccine	GBS	$210.75
12	H1N1 Vaccine	GBS	$2,360.84
13	H1N1 Vaccine	GBS	$2,364.55
14	H1N1 Vaccine	GBS	$3,534.00
15	H1N1 Vaccine	GBS	$6,966.40
16	H1N1 Vaccine	GBS	$553,945.53
17	H1N1 Vaccine	GBS	$7,623.45
18	H1N1 Vaccine	GBS	$2,295,929.61
19	H1N1 Vaccine	GBS	$13,581.93
20	H1N1 Vaccine	GBS	$27,378.82
21	H1N1 Vaccine	GBS	$5,677.77
22	H1N1 Vaccine	GBS	$127,435.39
23	H1N1 Vaccine	GBS	$30.93
24	H1N1 Vaccine	GBS	$3,500.00

25	H1N1 Vaccine	GBS	$38.00
26	H1N1 Vaccine	GBS	$2,316.00
27	H1N1 Vaccine	GBS	$571,635.25
28	H1N1 Vaccine	GBS	$49,759.00
29	H1N1 Vaccine	GBS	$220.00
Total			**$6,076,087.47**

Table 3. CICP Claims Eligible for Compensation, but No Eligible Reported Losses or Expenses (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was eligible for compensation, but did not have eligible reported losses or expenses.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number ⬍	Alleged Countermeasure ⬍	Alleged Injury ⬍
1	H1N1 Vaccine	GBS
2	H1N1 Vaccine	GBS
3	Smallpox Vaccine	Myocarditis
4	H1N1 Vaccine	Anaphylaxis
5	H1N1 Vaccine	GBS
6	Smallpox Vaccine	Serum sickness
7	H1N1 Vaccine	Herpes Zoster Outbreak
8	H1N1 Vaccine	GBS
9	H1N1 Vaccine	GBS
10	H1N1 Vaccine	GBS

Table 4. CICP Claims Denied Compensation Because Required Medical Records Were Not Submitted (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was denied compensation because the requester did not submit any required medical records, which may include not submitting any of the medical records specified in their Authorization for Use or Disclosure of Health Information Form(s) submitted to the Program. When this occurs, CICP staff notify the requester and provide them an opportunity to submit the appropriate medical records. However, if the appropriate medical records are not received, CICP staff are unable to conduct a medical review of the claim. If medical records documenting the alleged injury are received, the claim will proceed to a medical review even if incomplete after the requester has had an opportunity to submit the additional appropriate medical records.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number ⬍	Alleged Countermeasure ⬍	Alleged Injury ⬍
1	H1N1 vaccine	Anaphylaxis
2	H1N1 vaccine	Rash (Arm/Shoulder)

Number	Alleged Countermeasure	Alleged Injury
3	H1N1 vaccine	Rash (Upper Torso/Scalp)
4	H1N1 vaccine	Flu Symptoms
5	H1N1 vaccine	Not Specified
6	H1N1 vaccine	Flu Symptoms
7	H1N1 vaccine	Flu Symptoms
8	H1N1 vaccine	Not Specified
9	H1N1 vaccine	Fever/ Difficulty Breathing
10	H1N1 vaccine	Anaphylaxis
11	H1N1 vaccine	Flu Symptoms
12	H1N1 vaccine	Fever / Vomiting / Shortness of Breath
13	H1N1 vaccine	GBS
14	H1N1 vaccine	Neurologic symptoms
15	H1N1 vaccine	Flu Symptoms
16	H1N1 vaccine	Polyarthritis
17	H1N1 vaccine	Gastroenteritis
18	H1N1 vaccine	Allergic Reaction
19	H1N1 vaccine	Miscarriage
20	H1N1 vaccine	Bell's Palsy
21	H1N1 vaccine	Weakness/ Elevated Blood Pressure
22	H1N1 vaccine	Arm Pain
23	H1N1 vaccine	Hematoma
24	H1N1 vaccine	Rapid Heartbeat / Dizziness
25	H1N1 vaccine	Allergic Reaction
26	H1N1 vaccine	Allergic Reaction
27	H1N1 vaccine	Allergic Reaction
28	H1N1 vaccine	Allergic Reaction
29	H1N1 vaccine	Not Specified
30	H1N1 vaccine	Allergic Reaction
31	H1N1 vaccine	Transverse Myelitis
32	H1N1 vaccine	Allergic Reaction
33	H1N1 vaccine	Allergic Reaction

Number	Alleged Countermeasure	Alleged Injury
34	H1N1 vaccine	GBS
35	H1N1 vaccine	Not Specified
36	H1N1 vaccine	Lymph Node Enlargement
37	H1N1 vaccine	Myalgias
38	H1N1 vaccine	Not Specified
39	H1N1 vaccine	Idiopathic Thrombocytopenic Purpura (ITP)
40	H1N1 vaccine	Anaphylactic Shock
41	H1N1 vaccine	Not Specified
42	H1N1 vaccine	Allergic Reaction
43	H1N1 vaccine	Weakness/ Neurologic Issues
44	H1N1 vaccine	Miscarriage
45	H1N1 vaccine	Rotator Cuff Tear
46	H1N1 vaccine	Numbness/ Swelling
47	H1N1 vaccine	GBS
48	H1N1 vaccine	Edema/ Itching/ Rash/ Skin Lesions/ Weight loss
49	H1N1 vaccine	Autoimmune Encephalopathy
50	H1N1 vaccine	Cyst
51	H1N1 vaccine	Allergic Reaction
52	H1N1 vaccine	Wheezing / Fever
53	H1N1 vaccine	Fever/ Headache/ Severe Pain
54	H1N1 vaccine	Miscarriage
55	H1N1 vaccine	Miscarriage
56	H1N1 vaccine	Allergic Reaction
57	H1N1 vaccine	Bell’s Palsy
58	H1N1 vaccine	GBS
59	H1N1 vaccine	Not Specified
60	H1N1 vaccine	GBS
61	H1N1 vaccine	Obsessive Behavior/ Depression
62	H1N1 vaccine	Not Specified
63	H1N1 vaccine	GBS
64	H1N1 vaccine	Miscarriage

Number	Alleged Countermeasure	Alleged Injury
65	H1N1 vaccine	Diabetes
66	H1N1 vaccine	Allergic Reaction
67	H1N1 vaccine	Neurologic symptoms
68	H1N1 vaccine	Pain at Injection Site
69	H1N1 vaccine	Miscarriage
70	H1N1 vaccine	Fatigue / Spasms
71	H1N1 vaccine + Tamiflu + Relenza	Severe Cough
72	H1N1 vaccine	Pain / Weakness
73	H1N1 vaccine	Severe Cough
74	H1N1 vaccine	Autoimmune Reaction
75	H1N1 vaccine	Not Specified
76	H1N1 vaccine	Allergic Reaction
77	H1N1 vaccine	Headaches / Severe Pain
78	H1N1 vaccine	Headaches / Severe Pain
79	H1N1 vaccine	Peripheral Neuropathy / Paresthesia
80	H1N1 vaccine	Not Specified
81	H1N1 vaccine	Pain / Numbness
82	H1N1 vaccine	Difficulty Breathing
83	H1N1 vaccine	Rash
84	H1N1 vaccine	Not Specified
85	H1N1 vaccine	Miscarriage
86	H1N1 vaccine	Numbness / Pain
87	H1N1 vaccine	Not Specified
88	H1N1 vaccine	Viral Illness
89	H1N1 vaccine	Pneumonia
90	H1N1 vaccine	Not Specified
91	H1N1 vaccine	Hives
92	H1N1 vaccine	Shoulder Severe Pain
93	H1N1 vaccine	Shoulder Pain
94	H1N1 vaccine	Heart Arrhythmia / Syncope/ Seizures/ Stroke

Number	Alleged Countermeasure	Alleged Injury
95	H1N1 vaccine	Not Specified
96	H1N1 vaccine	Polymyositis/ Fibromyalgia
97	H1N1 vaccine	Breathing Issues
98	H1N1 vaccine	Neurologic symptoms
99	H1N1 vaccine	Not Specified
100	H1N1 vaccine	Pain / Nausea / Numbness
101	H1N1 vaccine	GBS
102	H1N1 vaccine	Neuropathy / Dizziness / Fatigue
103	H1N1 vaccine	Not Specified
104	H1N1 vaccine	Not Specified
105	H1N1 vaccine	Not Specified
106	H1N1 vaccine	Not Specified
107	H1N1 vaccine	Rotator Cuff Tear / Tendonitis / Nerve Damage
108	H1N1 vaccine	Flu Symptoms
109	H1N1 vaccine	Not Specified
110	H1N1 vaccine	Death
111	H1N1 vaccine	Paralysis
112	H1N1 vaccine	Immobility / Shoulder pain
113	H1N1 vaccine	Rheumatoid Arthritis / Raynaud's Syndrome
114	H1N1 vaccine	Breathing Issues / Coughing
115	H1N1 vaccine	Pain at Injection Site
116	H1N1 vaccine	Shoulder Pain / Weakness
117	H1N1 vaccine	Pain / Spasms
118	H1N1 vaccine	Numbness / Soreness / Spasms
119	H1N1 vaccine	GBS
120	H1N1 vaccine	Weakness / Numbness
121	Anthrax vaccine	GBS
122	H1N1 vaccine	Paralysis / Numbness / Pain
123	H1N1 vaccine	Paralysis / Pain
124	H1N1 vaccine	Chest Pain

Number	Alleged Countermeasure	Alleged Injury
125	H1N1 vaccine	Bradycardia / Postural Orthostatic Tachycardia Syndrome (POTS) / Hypertension / Headache
126	Smallpox vaccine	GBS
127	Smallpox vaccine	Myocarditis
128	Smallpox vaccine	Pain / Allergic Reaction
129	Anthrax Vaccine	Encephalitis / Seizures
130	H1N1 vaccine	Not Specified
131	Smallpox vaccine	Allergic Reaction
132	Anthrax vaccine	Allergic Reaction / Nervous system Disorder / Thyroid Cancer
133	H1N1 vaccine	GBS / Death
134	Anthrax vaccine	Myocarditis
135	H7N9 Drug Trial	Heart Palpitations

Table 5. CICP Claims Denied Compensation for Not Meeting the Standard of Proof and/or a Covered Injury Was Not Sustained (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was denied compensation because the standard of proof for causation was not met and/or a covered injury was not sustained. To be eligible for CICP benefits, a requester must show that a covered serious physical injury was sustained as the direct result of the administration or use of a covered countermeasure. **The CICP may only make such determinations based on compelling, reliable, valid, medical and scientific evidence.** A covered injury is a serious physical injury (which, as a general matter, is an injury that warranted hospitalization, whether or not the person was actually hospitalized, or that led to a significant loss of function or disability, whether or not hospitalization was warranted), or death, determined to be:

1. An injury meeting the requirements of a covered countermeasures injury table, unless there is another more likely cause; or
2. An injury (or its health complications) that is the direct result of the administration or use of a covered countermeasure. This includes serious aggravation caused by a covered countermeasure of a pre-existing condition.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	H1N1 vaccine	Headaches/ Breathing Difficulty
2	H1N1 vaccine	Eosinophilic Esophagitis
3	H1N1 vaccine	Allergic Reaction
4	H1N1 vaccine	Hearing Loss
5	H1N1 vaccine	Allergic Reaction
6	H1N1 vaccine	Paralysis / Weakness
7	H1N1 vaccine	Allergic Reaction
8	H1N1 vaccine	ITP
9	H1N1 vaccine	Flu Symptoms

Number	Alleged Countermeasure	Alleged Injury
10	H1N1 vaccine	Flu Symptoms
11	H1N1 vaccine	Abdominal Pain
12	H1N1 vaccine	Acute Cardiopulmonary Arrest
13	H1N1 vaccine	Neuropathy
14	H1N1 vaccine	Transverse Myelitis
15	H1N1 vaccine	Flu Symptoms
16	H1N1 vaccine	Bronchitis
17	H1N1 vaccine	Asthma
18	H1N1 vaccine	Transverse Myelitis
19	H1N1 vaccine	Connective Tissue Disease
20	H1N1 vaccine	Premature Labor
21	H1N1 vaccine	Migraine Headaches
22	H1N1 vaccine	Flu Symptoms
23	H1N1 vaccine	Neuropathy
24	H1N1 vaccine	Fibromyalgia / Groves Disease
25	H1N1 vaccine	Allergic Hepatitis
26	H1N1 vaccine	Allergic Reaction
27	H1N1 vaccine	A-Fib / Difficulty Breathing
28	H1N1 vaccine	Pain / Numbness
29	H1N1 vaccine	GBS
30	H1N1 vaccine	Neuropathy
31	H1N1 vaccine	Acute Disseminated Encephalomyelitis (ADEM)
32	H1N1 vaccine	GBS
33	H1N1 vaccine	GBS
34	H1N1 vaccine	Hyperthyroidism
35	H1N1 vaccine	Upper Respiratory Infection
36	H1N1 vaccine	Paresthesias
37	H1N1 vaccine	GBS
38	H1N1 vaccine	Allergic Reaction
39	H1N1 vaccine	Movement Disorder
40	H1N1 vaccine	Migraine Headaches

Number	Alleged Countermeasure	Alleged Injury
41	H1N1 vaccine	Death
42	H1N1 vaccine	Muscle Strain
43	H1N1 vaccine	Bell's Palsy
44	H1N1 vaccine	Death
45	H1N1 vaccine	Miscarriage
46	H1N1 vaccine	Headaches / Shortness of Breath / Miscarriage
47	H1N1 vaccine	Neurologic symptoms
48	H1N1 vaccine	Not Specified
49	H1N1 vaccine	GBS
50	H1N1 vaccine	GBS
51	H1N1 vaccine	Optic Neuritis
52	H1N1 vaccine	GBS / Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
53	H1N1 vaccine	Allergic Reaction
54	H1N1 vaccine	Miscarriage
55	H1N1 vaccine	Neuropathy
56	H1N1 vaccine	Anaphylactic Shock
57	H1N1 vaccine	Stroke
58	H1N1 vaccine	Weakness / Heart Palpitations
59	H1N1 vaccine	Abdominal Pain
60	H1N1 vaccine	Bronchitis / Pneumonia / Shoulder Pain/ Weakness
61	H1N1 vaccine	Seizures / Fatigue
62	H1N1 vaccine	CIDP
63	H1N1 vaccine	Idiopathic Polyneuropathy
64	H1N1 vaccine	Henoch Schonlein Purpura (HSP)
65	H1N1 vaccine	Ocular Migraine
66	H1N1 vaccine	Allergic Reaction
67	H1N1 vaccine	Miscarriage
68	H1N1 vaccine	Myocarditis
69	H1N1 vaccine	Miscarriage
70	H1N1 vaccine	Rash
71	H1N1 vaccine	Pneumonia

Number	Alleged Countermeasure	Alleged Injury
72	H1N1 vaccine	Rash / Hives
73	H1N1 vaccine	Rheumatoid Arthritis / Fatigue / Pain/ Headaches
74	H1N1 vaccine	GBS Symptoms / Nausea
75	H1N1 vaccine	Small Fiber Neuropathy
76	H1N1 vaccine	Small Fiber Neuropathy
77	H1N1 vaccine	Weakness / Low Blood Pressure / Rapid Heartbeat
78	H1N1 vaccine	Seizures
79	H1N1 vaccine	GBS
80	H1N1 vaccine	Hives / Brain Swelling
81	H1N1 vaccine	GBS
82	H1N1 vaccine	Nerve Damage
83	H1N1 vaccine	Peripheral neuropathy
84	H1N1 vaccine	Gastroparesis
85	H1N1 vaccine	Chronic Pain
86	H1N1 vaccine	Fever / Pain / Weakness / Swelling/ Fatigue
87	H1N1 vaccine	Death
88	H1N1 vaccine	Vertigo
89	H1N1 vaccine	Adhesive Capsulitis
90	H1N1 vaccine	Flu
91	H1N1 vaccine	Allergic Reaction
92	H1N1 vaccine	GBS
93	H1N1 vaccine	Miscarriage
94	H1N1 vaccine	Tachycardia
95	H1N1 vaccine	GBS
96	H1N1 vaccine	Weakness/ Swelling
97	H1N1 vaccine	GBS Symptoms
98	H1N1 vaccine	Damage to Auto-Immune System
99	H1N1 vaccine	Pharyngitis / Tachycardia
100	H1N1 vaccine	CIDP
101	H1N1 vaccine	Muscle Pain
102	H1N1 vaccine	Transverse Myelitis

Number	Alleged Countermeasure	Alleged Injury
103	H1N1 vaccine	Bell's Palsy
104	H1N1 vaccine	Pneumonia
105	H1N1 vaccine	Headaches / Paresthesias
106	H1N1 vaccine	Dizziness / Weakness
107	H1N1 vaccine	Numbness / Hypertension/ Brachial Neuritis
108	H1N1 vaccine	CIDP
109	H1N1 vaccine	Transverse Myelitis
110	H1N1 vaccine	Anaphylaxis / Pneumonia
111	H1N1 vaccine	ITP
112	H1N1 vaccine	Multiple Sclerosis
113	H1N1 vaccine	Asthma / Pneumonia
114	H1N1 vaccine	Serum Sickness
115	H1N1 vaccine	Pain / Weakness
116	H1N1 vaccine	Tingling
117	H1N1 vaccine	Indigestion
118	H1N1 vaccine	Brachial Plexus
119	H1N1 vaccine	Eye Problems
120	H1N1 vaccine	GBS
121	H1N1 vaccine	Fibromyalgia
122	H1N1 vaccine	Wheezing / Fatigue / Weakness
123	H1N1 vaccine	Paralysis
124	H1N1 vaccine	Conversion Disorder
125	H1N1 vaccine	Flu-like Symptoms
126	H1N1 vaccine	Brain Lesions
127	H1N1 vaccine	CIDP
128	H1N1 vaccine	Polyarthritis
129	H1N1 vaccine	Shoulder Pain/ Ovarian Cyst
130	H1N1 vaccine	Neuropathy
131	H1N1 vaccine	Delusions
132	H1N1 vaccine	Pain / Nausea / Weakness / Numbness / Fatigue
133	H1N1 vaccine	Myocarditis

Number	Alleged Countermeasure	Alleged Injury
134	H1N1 vaccine	Vasculitis / Renal Failure
135	H1N1 vaccine	GBS
136	H1N1 vaccine	GBS
137	H1N1 vaccine	GBS
138	H1N1 vaccine	Boil
139	H1N1 vaccine	CIDP
140	H1N1 vaccine	Acute Disseminated Encephalomyelitis (ADEM)
141	H1N1 vaccine	Encephalitis / Seizures
142	H1N1 vaccine	Tinnitus / Hearing Loss
143	H1N1 vaccine	Reflex Sympathetic Dystrophy, Meningitis
144	H1N1 vaccine	Dyspnea / Severe Pain
145	H1N1 vaccine	Transverse Myelitis
146	H1N1 vaccine	Myalgias
147	H1N1 vaccine	Anaphylactic Shock
148	H1N1 vaccine	Fever / Loss of Consciousness
149	H1N1 vaccine	Weakness / Severe Pain / Migraine
150	H1N1 vaccine	GBS
151	H1N1 vaccine	Weakness / Neurologic Issues
152	H1N1 vaccine	GBS
153	H1N1 vaccine	GBS
154	H1N1 vaccine	GBS
155	H1N1 vaccine	Acute Kidney Injury
156	H1N1 vaccine	Chronic Fatigue Syndrome
157	H1N1 vaccine	Neurologic symptoms
158	H1N1 vaccine	Death
159	H1N1 vaccine	Death
160	H1N1 vaccine	Serum Sickness
161	H1N1 vaccine	Weakness / Numbness / Pain
162	H1N1 vaccine	High Blood Pressure
163	H1N1 Vaccine	Hearing Loss
164	H1N1 vaccine	Seizures / Encephalopathy

Number	Alleged Countermeasure	Alleged Injury
165	H1N1 vaccine	Numbness / Pain / Tremors/ Nausea
166	H1N1 vaccine	Speech Loss
167	H1N1 vaccine	Parethesias
168	H1N1 vaccine	Numbness / Weakness / Fatigue
169	H1N1 vaccine	Weakness / Swelling
170	H1N1 vaccine	Hearing Loss
171	H1N1 vaccine	Severe Pain
172	H1N1 vaccine	Rash / Swelling / Fever
173	H1N1 vaccine	Swelling/ Miscarriage / Rash/ Swollen Lymph Nodes
174	H1N1 vaccine	Allergic Reaction
175	H1N1 vaccine	Henoch Schonlein Purpura (HSP)
176	H1N1 vaccine	Autonomic Dysfunction
177	H1N1 vaccine	Bell's Palsy
178	H1N1 vaccine	Arm Pain / Edema / Blurry Vision
179	H1N1 vaccine	Brain Elisions / Weakness / Paralysis
180	H1N1 vaccine	Acquired Hemophilia A
181	H1N1 vaccine	Acute Transverse Myelitis
182	H1N1 vaccine	Seizures
183	H1N1 vaccine	Seizures
184	H1N1 vaccine	GBS
185	H1N1 vaccine	GBS
186	H1N1 vaccine	Seizures
187	H1N1 vaccine	GBS
188	H1N1 vaccine	GBS
189	H1N1 vaccine	Headaches / Tremors / Nausea / Dizziness
190	H1N1 vaccine	Serum Sickness
191	H1N1 vaccine	Death
192	H1N1 vaccine	Encephalopathy
193	H1N1 vaccine	Pain
194	H1N1 vaccine	Seizures
195	H1N1 vaccine	Not Specified

Number	Alleged Countermeasure	Alleged Injury
196	H1N1 vaccine	Fever
197	H1N1 vaccine	GBS
198	H1N1 vaccine	GBS
199	H1N1 vaccine	Brachial Neuritis
200	H1N1 vaccine	Bronchitis
201	H1N1 vaccine	Cellulitis
202	H1N1 vaccine	Rheumatoid Arthritis
203	H1N1 vaccine	Interstitial Cystitis / Celiac Sprue
204	H1N1 vaccine	CIDP
205	H1N1 vaccine	Fibromyalgia / Lyme Disease
206	H1N1 vaccine	GBS
207	H1N1 vaccine	Bell's Palsy
208	H1N1 vaccine	Rash
209	H1N1 vaccine	GBS
210	H1N1 vaccine	Myositis
211	H1N1 vaccine	Leg Pain / Weakness / Anxiety
212	H1N1 vaccine	CIDP
213	H1N1 vaccine	GBS
214	Anthrax vaccine	Undifferentiated Connective Tissue Disease
215	Anthrax vaccine	Headaches
216	H5N1 vaccine	Esophagitis
217	H1N1 vaccine	Seizures / Brain Damage
218	Anthrax vaccine	Allergic Reaction
219	Smallpox vaccine / Anthrax vaccine	Hypertension
220	Anthrax vaccine	Serum Sickness
221	Smallpox vaccine	Death
222	Smallpox vaccine	Pain / Itching
223	Smallpox vaccine	Hand Tingling, Headache, Chest Pain, Drowsiness, Disorientation
224	Anthrax vaccine	Myalgia

Alleged COVID-19 Countermeasures

Number	Alleged Countermeasure	Alleged Injury

Number	Alleged Countermeasure	Alleged Injury
225	Ventilator	Death
226	COVID-19 Vaccine	Swelling of the Tongue and Throat, Difficulty Speaking and Swallowing and Dizziness
227	COVID-19 Vaccine	SIRVA

Table 6. CICP Ineligible Claims due to Missing the Filing Deadline (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was ineligible because the Request for Benefits (claim) was not filed within the 1-year filing deadline. The claim must be filed within 1 year after the date of the administration or use of the covered countermeasure alleged to have caused the injury or within 1 year after the effective date of the establishment of, or amendment to, a countermeasure injury table.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	Anthrax vaccine	Epilepsy/ Seizures
2	Anthrax vaccine	Pain/ Blisters
3	H1N1 vaccine	Anxiety Attack
4	H1N1 vaccine	Bilateral Brachial plexus
5	H1N1 vaccine	Bradycardia
6	H1N1 vaccine	CIDP
7	H1N1 vaccine	Fatigue / Fibromyalgia / Brachial Neuritis
8	H1N1 vaccine	GBS
9	H1N1 vaccine	GBS
10	H1N1 vaccine	Miscarriage
11	H1N1 vaccine	Myopericarditis
12	H1N1 vaccine	Narcolepsy
13	H1N1 vaccine	Neurologic symptoms
14	H1N1 vaccine	Not Specified
15	H1N1 Vaccine	Numbness / Amputation
16	H1N1 vaccine	Numbness / Metallic Taste
17	H1N1 vaccine	Optic Neuritis
18	H1N1 vaccine	Pain / Weakness
19	H1N1 vaccine	Paralysis
20	H1N1 vaccine	Paralysis / Severe Pain
21	H1N1 vaccine	Pericarditis
22	H1N1 vaccine	Pneumonia / Edema/ Paralysis/ Confusion

Number	Alleged Countermeasure	Alleged Injury
23	H1N1 vaccine	Postural Orthostatic Tachycardia Syndrome (POTS)
24	H1N1 vaccine	Rash
25	H1N1 vaccine	Rheumatoid Arthritis
26	H1N1 vaccine	Seizures
27	H1N1 vaccine	Severe Arm Pain
28	H1N1 vaccine	Severe Pain
29	H1N1 vaccine	Shoulder Pain
30	H1N1 vaccine	Vision Problems / Paralysis
31	H1N1 vaccine	Weakness / Severe Pain
32	H1N1 vaccine	Weakness / Neurologic Issues
33	H1N1 vaccine	Vasculitis / Tendonitis / Polymyalgia Rheumatica
34	H1N1 vaccine	Transverse Myelitis
35	Smallpox vaccine	Pericarditis
36	Smallpox vaccine	Not Specified
37	Smallpox vaccine	Heart Swelling / High Blood Pressure/ Paralysis
38	Smallpox Vaccine, Anthrax Vaccine	Severe Ulcerative Colitis

Table 7. Ineligible Claims for Products Not Covered by the CICP (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was ineligible because the Request for Benefits (claim) alleged an injury from a product that the CICP does not cover.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	1976 H1N1 vaccine	GBS
2	1976 H1N1 vaccine	GBS
3	Pre-Prep Act Anthrax vaccine	Fatigue/ Fibromyalgia/ Depression/ Lesions
4	Pre-Prep Act Anthrax vaccine	Migraine Headaches
5	Pre-Prep Act Anthrax vaccine	Migraine Headaches
6	Pre-Prep Act Anthrax vaccine	Migraine Headaches / Pain / Diarrhea
7	Pre-Prep Act Anthrax vaccine	Nerve Disorder / Sleep Disorder
8	Pre-Prep Act Anthrax vaccine	Neuropathy / Central Nervous System Demyelinating Disease / Inflammatory Joint Disease / Fatigue
9	Pre-Prep Act Anthrax vaccine	Not Specified

Number	Alleged Countermeasure	Alleged Injury
10	Pre-Prep Act Anthrax vaccine	Diarrhea / Fatigue / Asthma
11	Pre-Prep Act Anthrax vaccine	Myofacial Pain Syndrome / SLE Lupus / Scoliosis / SI Joint Dysfunction / IBS Syndrome / Night Sweats / Psychosis
12	DTAP, MMR vaccines	Minimal Change Disease
13	DTAP, Polio, and Haemoplilus Influenzae B vaccines	Seizures / Infantile Spasms / Delayed Development
14	Human Papillomavirus (HPV) Vaccine	Enlarged Lymph Nodes/ Spleen and Liver
15	HPV vaccine	Neurologic Symptoms
16	Influenza / Pneumococcal Vaccines	Allergic Reaction
17	Japanese Encephalitis vaccine	Weakness/ Neurologic Issues
18	Meningococcal vaccine	Double Vision
19	Meningococcal vaccine	Shoulder Pain
20	Pneumococcal Vaccine	Pain/ Fever/ Inflammation
21	Pneumococcal vaccine	Fainting
22	Pneumococcal vaccine	Not Specified
23	Seasonal Flu vaccine	Arm Pain
24	Seasonal Flu vaccine	Arm Swelling
25	Seasonal Flu vaccine	Bipolar Disorder/ Depression
26	Seasonal Flu vaccine	Birth Defects
27	Seasonal Flu vaccine	Calcified Tendons/ Arthritis symptoms
28	Seasonal Flu vaccine	CIDP
29	Seasonal Flu vaccine	Death
30	Seasonal Flu vaccine	Flu-like Symptoms
31	Seasonal Flu vaccine	Flu-like Symptoms
32	Seasonal Flu vaccine	Frozen Shoulder Syndrome
33	Seasonal Flu vaccine	GBS
34	Seasonal Flu vaccine	GBS
35	Seasonal Flu vaccine	Headache / Tremors / Fever
36	Seasonal Flu vaccine	Laryngitis
37	Seasonal Flu vaccine	Neurologic symptoms
38	Seasonal Flu vaccine	Not Specified
39	Seasonal Flu vaccine	Numbness / Weakness / Headaches/ Double Vision

Number	Alleged Countermeasure	Alleged Injury
40	Seasonal Flu vaccine	Paralysis
41	Seasonal Flu vaccine	Paralysis / Pain
42	Seasonal Flu vaccine	Paralysis / Pain
43	Seasonal Flu vaccine	Paresthesia / Weakness / Tremors
44	Seasonal Flu vaccine	Severe Arm Pain
45	Seasonal Flu vaccine	Shoulder Pain
46	Seasonal Flu vaccine	Shoulder Pain
47	Seasonal Flu vaccine	Stevens Johnson Syndrome
48	Seasonal Flu vaccine	GBS
49	Shingles vaccine	Immobility / Fibromyalgia / Depression
50	Shingrix vaccine	Pain
51	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Boils / Stroke / High Blood Pressure / Arthritis
52	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Not Specified
53	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Organic Brain Syndrome / Neuropathy
54	Tetanus, Diphtheria, Acellular Pertussis (TDAP) Vaccine	Arm Pain

Table 8. CICP Ineligible Claims Due to Not Alleging Any Countermeasure Administration or Use (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that is ineligible because the Request for Benefits did not allege the administration or use of any countermeasure.

Number	Alleged Countermeasure	Alleged Injury
1	Not Specified	Weakness/ Neurologic Issues

Date Last Reviewed: October 2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 05, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

2nd Letter Subject: Final Response Letter

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your September 02, 2021, Freedom of Information Act (FOIA) request on September 02, 2021, seeking:

> "Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected."

A search of our records failed to reveal any documents pertaining to your request. The CDC Emergency Operations Center (EOC) conveyed that this information is not collected.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by February 03, 2022.

Sincerely,

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#21-02152-FOIA

Infection fatality rate of COVID-19 in community-dwelling populations with emphasis on the elderly: An overview

PREPRINT

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ABSTRACT

Background: The infection fatality rate (IFR) of Coronavirus Disease 2019 (COVID-19) varies widely according to age and residence status.

Purpose: Estimate the IFR of COVID-19 in community-dwelling elderly populations and other age groups from seroprevalence studies. Study protocol: https://osf.io/47cgb.

Data Sources: Seroprevalence studies done in 2020 and identified by any of four existing systematic reviews.

Study Selection: SARS-CoV-2 seroprevalence studies with ≥1000 participants aged ≥70 years that presented seroprevalence in elderly people; aimed to generate samples reflecting the general population; and whose location had available data on cumulative COVID-19 deaths in elderly (primary cutoff ≥70 years; ≥65 or ≥60 also eligible).

Data Extraction: We extracted the most fully adjusted (if unavailable, unadjusted) seroprevalence estimates and sampling procedure details. We also extracted age- and residence-stratified cumulative COVID-19 deaths (until 1 week after the seroprevalence sampling midpoint) from official reports, and population statistics, to calculate IFRs corrected for unmeasured antibody types. Sample size-weighted IFRs were estimated for countries with multiple estimates. Secondary analyses examined data on younger age strata from the same studies.

Data Synthesis: Twenty-three seroprevalence surveys representing 14 countries were included. Across all countries, the median IFR in community-dwelling elderly and elderly overall was 2.4% (range 0.3%-7.2%) and 5.5% (range 0.3%-12.1%). IFR was higher with larger proportions of people >85 years. Younger age strata had low IFR values (median 0.0027%, 0.014%, 0.031%, 0.082%, 0.27%, and 0.59%, at 0-19, 20-29, 30-39, 40-49, 50-59, and 60-69 years).

Limitations: Biases in seroprevalence and mortality data.

Conclusions: The IFR of COVID-19 in community-dwelling elderly people is lower than previously reported. Very low IFRs were confirmed in the youngest populations.

INTRODUCTION

Most Coronavirus Disease 2019 (COVID-19) affect the elderly (1), and persons living in nursing homes are particularly vulnerable (2). Hundreds of seroprevalence studies have been conducted in various populations, locations, and settings. These data have been used and synthesized in several published efforts to obtain estimates of the infection fatality rate (IFR, proportion of deceased among those infected), and its heterogeneity (3-6). All analyses identify very strong risk-gradient based on age, although absolute risk values still have substantial uncertainty. Importantly, the vast majority of seroprevalence studies include very few elderly people (7). Extrapolating from seroprevalence in younger to older age groups is tenuous. Elderly people may genuinely have different seroprevalence. Ideally, elderly should be more protected from exposure/infection than younger people, although probably the ability to protect the elderly has varied substantially across countries (8). Moreover, besides age, comorbidities and lower functional status markedly affects COVID-19 death risk (9). Particularly elderly nursing home residents accounted for 30-70% of COVID-19 deaths in high-income countries in the first wave (2), despite comprising <1% of the population. IFR in nursing home residents has been estimated to as high as 25% (10). Not separating residents of nursing homes from the community-dwelling may provide an average that is too low for the former and too high for the latter. Moreover, ascertainment and reporting of COVID-19 cases and deaths in nursing home populations show considerable variation across countries (2), with potentially heavy bearing on overall mortality, while community-dwelling elderly data may be less unreliable (especially in high-income countries). Finally, seroprevalence estimates reflect typically community-dwelling populations (enrollment of nursing home residents is scarce/absent in serosurveys).

Here we estimated the COVID-19 IFR in community-dwelling populations at all locations where seroprevalence studies with many elderly individuals have been conducted. Primary emphasis

is on the IFR of the elderly. As a secondary analysis, we also explored the IFR of younger age-strata in these same studies.

METHODS

Data Sources and Searches

We identified seroprevalence studies (peer-reviewed publications, official reports, or preprints) in four existing systematic reviews (3, 7, 11, 12) as for a previous project (13), using the most recent updates of these reviews and their respective databases as of March 16, 2021. The protocol of this study was registered at the Open Science Framework (https://osf.io/47cgb) after piloting data availability in December 2020 but before extracting full data, communicating with local authorities and study authors for additional data and performing any calculations. Amendments to the protocol and their justification are described in Appendix Table 1.

Study Selection

We included studies on SARS-CoV-2 seroprevalence that had sampled at least 1000 participants aged ≥70 years in the location and/or setting of interest, provided an estimate of seroprevalence for elderly people, explicitly aimed to generate samples reflecting the general population, and were conducted at a location for which there is official data available on the proportion of cumulative COVID-19 deaths among elderly (with a cutoff placed between 60-70 years; e.g., eligible cutoffs were ≥70, ≥65, or ≥60, but not ≥75 or ≥55). Besides general population samples we also accepted studies focusing on patient cohorts (including residual clinical samples), insurance applicants, blood donors, and workers (excluding health care workers and others deemed to have higher than average exposure risk, since these would tend to overestimate seroprevalence). USA studies were excluded if they did not adjust seroprevalence for race or ethnicity, since these socio-economically related factors associate strongly with both study participation (14, 15) (blood donation, specific jobs, and insurance seeking) and COVID-19 burden (16-18). We focused on studies sampling participants in 2020, since IFRs in 2021 may be further affected by wide implementation of vaccinations (especially among the elderly) and by other changes (new variants and better treatment). Two authors reviewed records for eligibility. Discrepancies were solved by discussion.

Data Extraction

CA extracted each data point and JPAI independently verified the extracted data. Discrepancies were solved through discussion. For each location, we identified the age distribution of cumulative COVID-19 deaths and choose as primary age cutoff the one closest to 70, while placed between 60-70 years (e.g., ≥70, ≥65, or ≥60).

Similar to a previous project (3), we extracted from eligible studies information on location, recruitment and sampling strategy, dates of sample collection, sample size (overall and elderly group), and types of antibody measured (immunoglobulin G (IgG), IgM and IgA). We also extracted, for the elderly stratum, the estimated unadjusted seroprevalence, the most fully adjusted seroprevalence, and the factors considered for adjustment. Antibody titers may decline over time. E.g. a modelling study estimated 3-4 months average time to seroreversion (19). A repeated measurements study (20) suggests even 50% seroreversion within a month for asymptomatic/oligosymptomatic patients, although this may be an over-estimate due to initially false-positive antibody results. To address seroreversion, if there were multiple different time points of seroprevalence assessment, we selected the one with the highest seroprevalence estimate. If seroprevalence data were unavailable as defined by the primary cutoff, but with another eligible cutoff (e.g., ≥70, ≥65, or ≥60), we extracted data for that cut-off.

Population size (overall, and elderly) and numbers of nursing home residents for the location were obtained from multiple sources (see Appendix Table 2).

Cumulative COVID-19 deaths overall and in the elderly stratum (using the primary age cutoff) for the relevant location were extracted from official reports. The total number, i.e., confirmed and probable, was preferred whenever available. We extracted the accumulated deaths until 1 week after the midpoint of the seroprevalence study period, or the closest date with available data.

The proportion of cumulative COVID-19 deaths that occurred among nursing home residents for the relevant location and date was extracted from official sources or the International Long Term Care Policy Network (ILTCPN) report closest in time (2, 21). We preferred numbers recorded per residence status, i.e., including COVID-19 deaths among nursing home residents occurring in hospital. If the latter were unavailable, we calculated the total number of deaths in nursing home residents with a correction (by multiplying with the median of available ratios of deaths in nursing homes to deaths of nursing home residents in the ILTCPN 10/14/2020 report (2) for countries in the

same continent). We considered 95%, 98%, and 99% of nursing home residents' deaths to have occurred in people ≥70 years, ≥65 years and ≥60 years, respectively (22). For other imputations, see the online protocol.

Missing Data

We communicated with the authors of the seroprevalence study and with officers responsible for compiling the relevant official reports to obtain missing information or when information was available but not for the preferred age cut-offs. Email requests were sent, with two reminders to non-responders.

Calculated Data Variables

Infected and deceased community-dwelling elderly

The number of infected people among the community dwelling elderly for the preferred date (1 week after the midpoint of the seroprevalence study period) was estimated by multiplying the adjusted estimate of seroprevalence and the population size in community-dwelling elderly. We used unadjusted seroprevalence, when adjusted estimates were unavailable. We applied a non-prespecified correction for studies that excluded persons with diagnosed COVID-19 from sampling, primarily by using study authors' corrections, secondarily by adding the number of identified COVID-19 cases in community-dwelling elderly for the location up to the seroprevalence study midpoint.

The total number of fatalities in community-dwelling elderly was obtained by total number of fatalities in elderly minus those accounted for by nursing home residents in the elderly stratum. If the elderly proportion or nursing home residents' share of COVID-19 deaths were only available for another date than the preferred one, we assumed that the proportions were stable between the time points.

IFR estimation

We present IFR with corrections for unmeasured antibodies (as previously described (3)) as well as uncorrected. When only one or two types of antibodies (among IgG, IgM, IgA) were used in the seroprevalence study, seroprevalence was corrected upwards (and inferred IFR downwards) by 10% for each non-measured antibody. We added a non-prespecified calculation of 95% confidence

intervals (CIs) of IFRs based on extracted or calculated 95% CIs from seroprevalence estimates (Appendix Table 1). CI estimates should be seen with caution since they depend on adequacy of seroprevalence adjustments.

Data Synthesis and Analysis

Statistical analyses were done using R version 4.0.2 (23). Similar to a previous overview of IFR-estimating studies (3), we estimated the sample size-weighted IFR of community-dwelling elderly for each country and then estimated the median and range of IFRs across countries. As expected, there was extreme heterogeneity among IFR estimates, thus weighted meta-analysis averages may not be meaningful.

We explored a seroreversion correction of the IFR by X^m-fold, where m is the number of months from the peak of the first epidemic wave in the specific location and X is 0.99, 0.95, and 0.90 corresponding to 1%, 5%, and 10% relative monthly rate of seroreversion. We also added a non-prespecified sensitivity analysis to explore the percentage increase in the cumulative number of deaths and IFR, if the cutoff was put two weeks (rather than 1 week) after the study midpoint.

We expected IFR would be higher in locations with a higher share of people ≥85 years old among the analyzed elderly stratum. Estimates of $\log_{10}$IFR) were plotted against the proportion of people ≥85 years old among the elderly (for population pyramid sources see Appendix Table 2.

Added Secondary Analyses

IFR in younger age-strata has become a very important question since we wrote the original protocol and the studies considered here offered a prime opportunity to assess IFR also in younger age strata. Among the included studies, whenever there were seroprevalence estimates and COVID-19 mortality data available for younger age groups, we complemented data extraction for all available age strata. Studies were excluded if no mortality data were available for any age stratum of maximum width 20 years and maximum age 70 years. We used the same time points as those selected for the elderly data. We included all age strata with a maximum width of 20 years and available COVID-19 mortality information. We corresponded the respective seroprevalence estimates for each age stratum with eligible mortality data. Consecutive strata of 1-5 years were merged to generate 10-year bins. For seroprevalence estimates we used the age strata that most fully

covered the age bin for which mortality data were available; or the youngest age groups seroprevalence data from the closest available group with any sampled persons ≤20 years were accepted. E.g. for Ward et al (24), eligible age strata were 0-19 (paired with seroprevalence data for 20-24), 20-24, 25-34, 35-44, 45-54, 55-64. Population statistics for each analyzed age bin were obtained from the same sources as for the elderly. For age strata with multiple estimates from the same country, we calculated the sample size-weighted IFR per country before estimating median IFRs across locations for age groups 0-19, 20-29, 30-39, 40-49, 50-59, and 60-69 years. IFR estimates were placed in these age groups according to their midpoint, regardless of whether they perfectly matched the age group or not, e.g. an IFR estimate for age 18-29 years was placed in the 20-29 years group.

RESULTS

Seroprevalence studies

By March 16, 2021, 1206 SARS-CoV-2 seroprevalence reports were available in the four systematic reviews. Screening and exclusions are shown in Appendix Figure 1 and Appendix Table 2. Twenty-two seroprevalence studies were included, one of which contained two separate surveys.

The 23 seroprevalence surveys (Table 1) (24-47) represented 14 countries (Americas n=6, Asia n=3, Europe n=14). Only three studies were conducted in middle-income countries (one in Dominican Republic, two in India) and the other 20 in high-income countries. Nineteen studies targeted general population participants, 2 enrolled blood donors (27, 30), 1 biobank participants (43), and 1 hemodialysis patients (46). Three studies excluded upfront persons with previously diagnosed COVID-19 from participating in their sample (35, 39, 47). Mid-sampling points ranged from April 2020 to November 2020). Sampling had a median length of 5.7 weeks (range 6 days to 5 months). The median number of elderly individuals tested was 1809 (range 1010-21953). Median seroprevalence was 3.2% (range 0.47%-25.2%). Adjusted seroprevalence estimates were available for 20/23 studies.

Mortality and population statistics

COVID-19 deaths and population data among elderly at each location are shown in Table 1 (for sources, see Appendix Table 3). The proportion of a location's total COVID-19 deaths that happened among elderly had a median of 53% (range 51%-62%) in middle-income countries and 86% (range 51%-96%) in high-income countries. The proportion of a location's total COVID-19 deaths that occurred in nursing home residents was imputed for middle-income countries, and had a median of 44% (range 20%-85%) in in high-income countries with available data (for Qatar, the number was imputed). One study (45) included only COVID-19 deaths that occurred in nursing homes and was corrected to reflect also the deaths among nursing home residents occurring in hospitals. Among the population, the elderly group comprised a median of 9% (range 6%-11%) in middle-income countries and 15% (range 0.6%-24%) in high-income countries. People residing in nursing homes were 0.08-0.20% of elderly in middle-income countries and a median of 4.7% (range 0.5%-9.1%) in high-income countries.

Additional data contributed

Additional information was obtained from authors and agencies on four studies for seroprevalence data (26, 29, 34, 46); three studies for mortality data (25, 26, 29); two studies for population data (25, 26); and five excluded studies (clarifying non-eligibility).

Calculated IFRs

For 5 countries with more than one IFR estimate available sample size-weighted average IFRs were calculated. In 14 countries, IFRs in community-dwelling elderly (Figure 1, Table 1) had a median of 2.4% (range 0.3%-7.2%). For 2 middle-income countries, IFR was 0.3% versus 2.8% (range 1.3%-7.2%) in 12 high-income countries. Figure 1 also shows 95% CIs for IFRs based on 95% CIs for seroprevalence estimates. Median IFR in all elderly for all 14 individual countries was 5.5% (range 0.3%-12.1%). In the 2 middle-income countries, IFR in all elderly was 0.3-0.4% and in 12 high-income countries it was 6.8% (range 2.3%-12.1%).

Sensitivity analyses exploring different rates of seroreversion appear in Appendix Table 4. For the scenario with 5% relative monthly seroreversion, median IFR in community-dwelling elderly was still 2.4% (range 0.3%-6.1%) across all countries (0.3% in 2 middle-income countries, and 2.7% in 12 high-income countries. For the sensitivity analysis that explored the percentage increase in IFR if a later cutoff was used for cumulative deaths (two weeks after study midpoint), data were available for 20/23 seroprevalence surveys. There was a median relative increase of 4%, and median IFR in community-dwelling elderly became2.5% (Appendix Table 5).

IFR in the elderly and proportion >85 years

There was steeply increasing IFR with larger proportions of people ≥85 years old (Figure 2). A regression of logIFR against the proportion of people ≥85 years old had a slope of 0.056 ($p=0.002$), and suggested IFR=0.62%, 1.18%, and 4.29% when the proportion of people >85 in the elderly group was 5%, 10%, and 20%, respectively.

IFR in younger age-strata

We could extract data and calculate IFR on another 84 age-strata observations from 19/23 seroprevalence surveys (three had no mortality data for any eligible non-elderly age stratum (25, 30, 35) and one sampled no individuals <65 years of age (44)). The 19 surveys came from 11 countries. For the age group 0-19 years, only five studies had sampled participants for seroprevalence in the corresponding age group (24, 29, 31, 38, 41); for the other studies, the closest available age group

was used. Across all countries (Figure 3), the median IFR was 0.0027%, 0.014%, 0.031%, 0.082%, 0.27%, and 0.59%, at 0-19, 20-29, 30-39, 40-49, 50-59, and 60-69 years, using data from 9, 9, 10, 9, 11, and 6 countries, respectively. Appendix Figure 1 visualizes these estimates against other, previously published evaluations of age-specific IFR.

DISCUSSION

The IFR of COVID-19 in elderly was found to vary widely at locations where seroprevalence studies have enrolled many elderly individuals. IFR in community-dwelling elderly was consistently lower than in elderly overall, and in countries where nursing homes are widely used, the difference was very substantial. In secondary analyses, the aggregated estimates show very low IFR estimates for younger age groups.

Early estimates of case fatality rate (CFR, ratio of deaths divided by *documented* infections) in the elderly were very high and they played an instrumental role in disseminating both fear and alacrity in dealing with this serious pandemic. Early estimates of CFR from China (48) described CFR of 8% in the age group 70-79 and 14.8% in those ≥80 years. Extremely high CFR estimates were also reported initially from Italy (49) and New York (50). However, the number of infected individuals was much larger than the documented cases (51). Therefore, IFR is much lower than CFR. We are aware of three previous evaluations of age-stratified IFR estimates that combine seroprevalence data with age-specific COVID-19 mortality statistics (4, 5, 52). Levin *et al* (4) is also the basis for the US CDC pandemic planning scenarios (53). Levin *et al* report IFR 4.6% at age 75, and 15% at age 85 (4) without separating nursing home deaths. The assessment was based on relatively sparse data for these age groups. The authors counted deaths four weeks after the midpoint of the seroprevalence sampling period, which is the longest among the evaluations, with the argument that there is large potential reporting lag (although available mortality statistics are commonly updated retrospectively for the date of death). Also, almost all included studies came from hard-hit locations, where IFR may be substantially higher (3). Selection bias for studies with higher seroprevalence and/or higher death counts (6) may explain why their estimates for middle-aged and elderly are substantially higher than ours.

O'Driscoll *et al* (5) modeled 22 seroprevalence studies, and carefully comment how outbreaks in nursing homes can drive overall population IFRs. For young and middle-aged groups, their estimates largely agree with those presented here. Their estimates for elderly are still higher than ours. For ages ≥65 years, their model uses data derived from one location (England) on deaths that did not occur in nursing homes and is validated against other locations with such statistics. This may overestimate the community-dwelling proportion, since deaths of nursing home residents occurring in hospitals are counted in the England community estimates. Conversely our evaluation adds granularity by using deaths in nursing home residents from many countries, and by using seroprevalence estimates from 23 serosurveys with many elderly individuals.

The Imperial College COVID-19 response team (52) presents much higher IFR estimates for elderly overall. They use a very narrowly selected subset of 10 studies in 9 countries, five of which had sampled >1000 elderly people. Their selection criteria required >100 deaths in the location at the seroprevalence study midpoint, which skews the sample towards heavily-hit areas and higher IFRs (6).

Some published studies also present IFRs in elderly people for single locations based on seroprevalence data, but these are unavoidably location-limited (see Appendix text).

For persons 0-19 years, the median IFR was one death per 37,000 persons with COVID-19 infection, followed by estimates of 1:7100 in ages 20-29, 1:3200 in ages 30-39, and 1:1200 in ages 40-49. The Imperial College study (52) has 5-10 times higher estimates for persons 0-19 years and 20-29 years old; otherwise estimates in age groups <50 years are fairly consistent across previous (4, 5) and current analyses despite methodological differences. Thus, they may be used for assessing risk-benefits, e.g. with specific vaccines (54) in young populations.

Both the age distribution and other characteristics of people within the elderly stratum vary between different countries. E.g., obesity is a major risk factor for poor outcome with COVID-19 infection and prevalence of obesity is only 4% in India versus 20-36% in high-income countries analyzed here. Besides differences in risk factor characteristics, documentation criteria for coding COVID-19 deaths may have varied non-trivially across countries. Under- and over-counting of COVID-19 deaths may have occurred even in countries with advanced health systems.

Given that nursing home residents account for many COVID-19 deaths (55), a location's overall IFR across all ages is largely dependent on how nursing homes were afflicted (5). Spread in nursing homes was disproportionately high in the first wave (8). The share of nursing home deaths decreased markedly in subsequent waves (55) in most high-income countries with some exceptions (e.g. Australia). This change may be reflected in a much lower IFR among the elderly and the entire population after the first wave. Improved treatments (e.g. dexamethasone), and less use of harmful treatments (e.g. hydroxychloroquine, improper mechanical ventilation) may also have decreased IFR substantially in late 2020 and in 2021. With vaccination being promoted preferentially for elderly and vulnerable individuals in 2021, IFR may have decreased even more sharply (6). New variants becoming dominant in 2021 may also be associated with further lower IFR. E.g., in the last week of June 2021, in the UK, where the delta mutation has spread widely, even CFR has been ~0.1%.

Our analysis has several limitations. First, seroprevalence estimates among elderly reported by the included studies could over- or underestimate the proportion infected. We explored adjusted estimates accounting for 1-10% relative seroreversion per month; however, higher seroreversion is likely (19, 20, 56). Higher seroreversion will affect more prominently studies carried out later in the pandemic. Also, the current estimates do not fully account for the unknown share of people who may have tackled the infection without generating detectable serum/plasma antibodies (e.g., by mucosal,

innate, or cellular immune mechanisms) (57-61). Sensitivity estimates for antibody assays typically use positive controls from symptomatic individuals with clinically manifest infection; sensitivity may be lower for asymptomatic infections. All seroprevalence studies may have substantial residual biases despite whatever adjustments (6). Even well-designed general population studies may specifically fail to reach and recruit highly vulnerable populations, e.g. disadvantaged groups, immigrants, homeless, and other people at high exposure risks and poor health.

Second, the number of deaths may be biased for various reasons (3) leading to potential under- or over-counting. Using excess mortality data is an alternative that has caveats, as those data depend heavily on the reference time period; availability in specific age groups can be restricted; and the proportion of deaths that is directly attributable to COVID-19 may be difficult to separate from indirect effects of the pandemic and adverse effects of measures taken. To match the date for seroprevalence sampling (i.e., seroconversion) with cumulative deaths is an exercise with assumptions. Our sensitivity analysis that extended with one week the cutoff for counting deaths showed a negligible change in the median IFR calculation. Most studies included in our analysis had been performed during periods at or after the end of the first wave.

Third, we acknowledge the risk of bias in seroprevalence studies, mortality statistics, and even population statistics. However, assessments of risk of bias are far from straightforward, as illustrated by the discrepant assessments of these seroprevalence studies by other teams (6).

Finally, most available studies come from hard-hit locations that tend to have high IFRs (6). Consideration of age strata diminishes this representativeness bias, but cannot eliminate it. E.g., most countries not represented in the available data may have a shift towards lower ages within the stratum of the elderly. This translates to lower IFR.

Moreover, with the exception of India, all countries analyzed here have population prevalence of obesity 1.5-3-fold higher than the global prevalence (13%); other major risk factors for poor COVID-19 outcome such as smoking history, diabetes, cardiovascular disease, and immunosuppression (9) are also far more common in the high-income countries included in our analysis than the global average. Global IFR may thus be substantially lower in both the elderly and the lower age strata than estimates presented herein.

This overview synthesis finds a consistently much lower IFR of COVID-19 in community-dwelling elderly than in elderly overall, a difference which is substantial in countries where nursing homes are an established form of residency. Very low IFR estimates were confirmed in younger groups (<50). For middle-aged groups and elderly, estimates were lower than in some previous influential work with biased methodological choices (4, 52), but in agreement with other work (5). The estimates presented here may serve as one of several key pieces of information underlying public health policy decisions. With better management and better preventive measures, in particular vaccines, hopefully IFR estimates have already decreased further.

DECLARATION OF INTERESTS

The authors have no conflicts of interest.

Role of the Funding Source

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TRANSPARENCY STATEMENT

The protocol, data, and code used for this analysis will be made available at the Open Science Framework upon publication: https://osf.io/47cgb.

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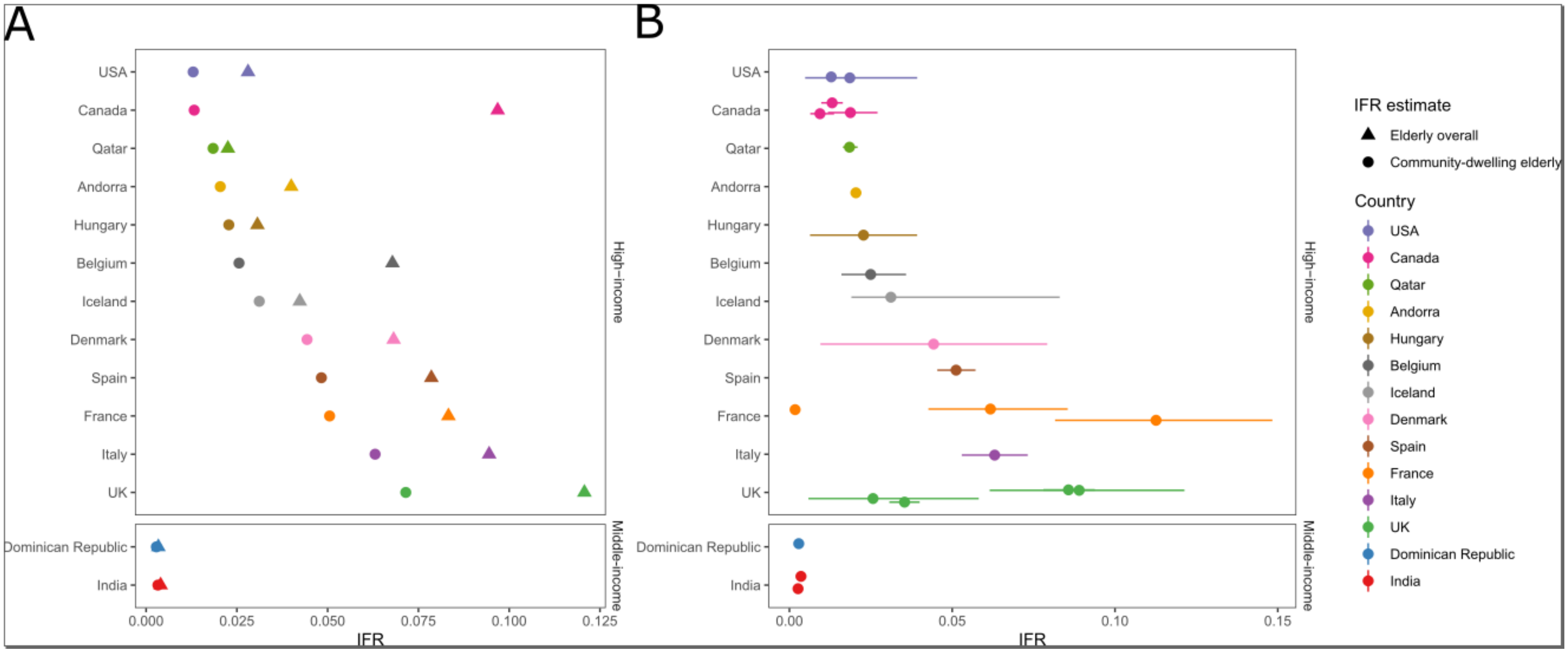
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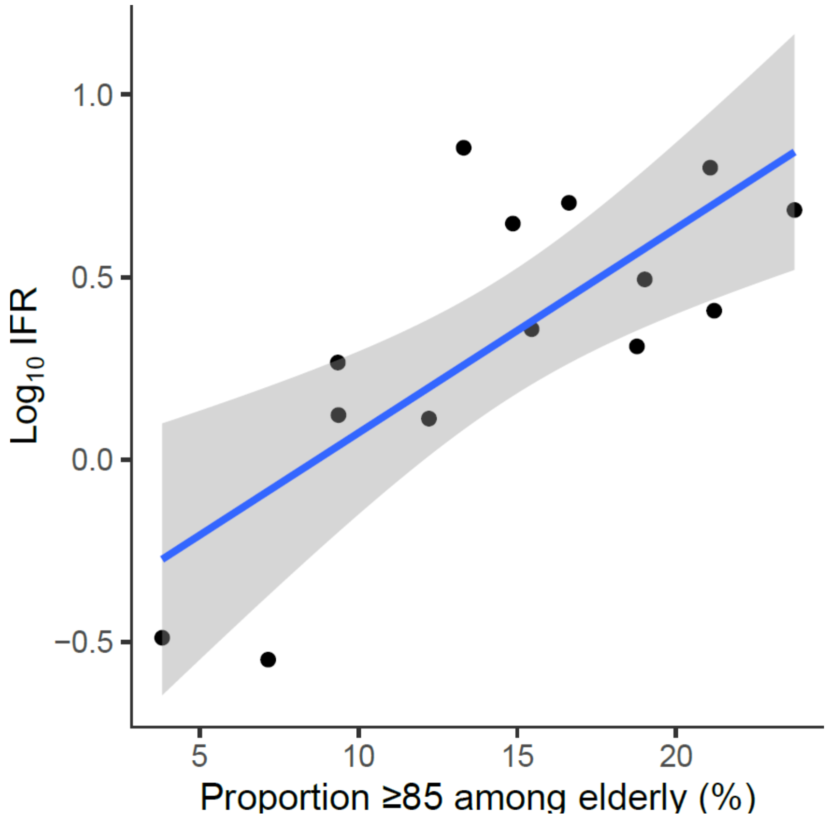
FIGURES

Figure 1. Infection fatality rates (IFRs) in elderly, corrected for unmeasured antibody types. **(A)** Countries' IFRs in community-dwelling elderly and elderly overall. **(B)** IFRs in community-dwelling elderly with 95% confidence intervals based on individual seroprevalence estimates and their uncertainty.



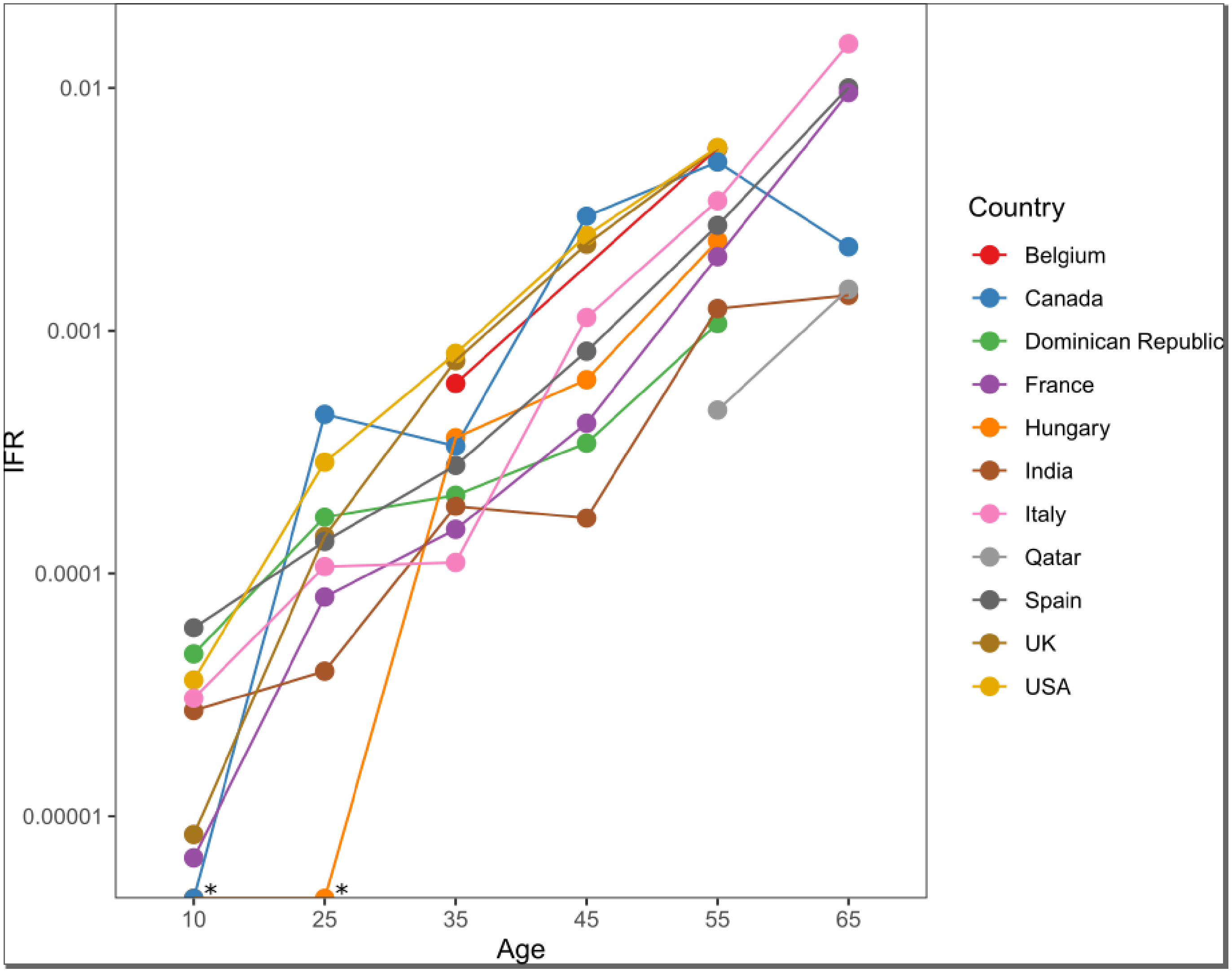
If multiple seroprevalence studies were available for the same country, we calculated the sample size-weighted IFR. For studies that did not report 95% confidence intervals, we complemented with a calculation using the number of sampled and seropositive elderly individuals. For those that provided adjusted estimates for age brackets (e.g., 70-79, 80-89, and 90+), we combined estimates for each study using a fixed effects inverse variance meta-analysis (of arcsine transformed proportions) to obtain 95% CIs.

Figure 2. Infection fatality rate, corrected for unmeasured antibody types, plotted against the proportion of people ≥85 years old among the elderly.



Log_{10} IFR: logarithm (with base 10) of the infection fatality rate. The "elderly" group is defined by the primary cutoff for each location. E.g. for Belgium 3% of the population is ≥85, and 13.6% of the population is ≥70, thus the proportion is 3/13.6. Imputation done for regional data: Denmark (3/5 regions), and Tamil Nadu, India, with country-level proportion of persons ≥85 years old among elderly.

Figure 3. Infection fatality rates in younger age groups derived from included seroprevalence studies.



IFRs are corrected for unmeasured antibody types. Sample size weighted IFRs were calculated for countries with multiple estimates available. * Infinite values produced by zero death counts.

TABLES

Table 1. Included seroprevalence studies with estimates of seroprevalence in the elderly, COVID-19 deaths in the elderly and community-dwelling elderly, and corrected infection fatality rate

Location (first author)	Sampling period	Number tested; number positive (n)	Age cutoff for mortality; age cutoff for seroprevalence (years)	Antibody type(s)	Adjusted seroprevalence; crude seroprevalence (%)	Adjustments	Deaths in community-dwelling elderly [all elderly] (n)	Population, community-dwelling elderly [all elderly] (n)	IFR community-dwelling elderly [all elderly] (%)
Andorra (Royo-Cebrecos)	May 4 to May 28	4339; 582	70; 70	IgG/IgM	NA; 13.41	None	22 [45]	7365 [7631]	2.04 [4]
Belgium (Herzog)	Mar 30 to Apr 5	1210; 29	70; 70	IgG	2.35; 2.4	Age, sex, province	1057 [3317]	1453426 [1581078]	2.56 [6.78]
Canada (Canadian Blood Services)	May 9 to June 18	9228; 66	60; 60	IgG	0.7; 0.72	Residential postal code, age, sex, sensitivity and specificity of the assay	867 [7359]	7828916 [8226145]	1.31 [10.56]
Canada (Tang / Ab-C Study)	July to September	1010; 14	70; 70	IgG	2.77; 1.39	Age, education levels	1299 [7958]	4112421 [4300000]	0.94 [5.52]
Ontario, Canada (Public Health Ontario)	June 5 to June 30	1236; 25	70; 70	IgG	1.77; 2.02	Population weighting and test characteristics	525 [2298]	1392596 [1513920]	1.76 [6.52]
Denmark (Pedersen)	June 2 to June 19	1201; 22	70; 70	IgG/IgM/IgA	1.4; 1.8	Sensitivity and specificity of the diagnostic assay; population size of recruitment areas (municipalities)	329 [531]	530764 [555882]	4.43 [6.82]
Dominican Republic (Paulino-	April to June	2739; 164	60; 60	IgG	NA; 5.97	None	237 [282]	1156877 [1158933]	0.28 [0.34]

Ramirez)									
France (INSERM)	May 13 to July 1 (75% before May 21)	2486; 83	65; 65	IgG	1.3; 3.34	Missing	12523 [26015]	12903996 [13440786]	6.17 [12.3]
Ile-de-France, France (Carrat)	May 4 to June 23 (90% of tests were performed May 4 to May 24)	1394; 52	70; 70	IgG	3.43; 3.73	Age, sex, socio-professional category	4297 [7712]	1279903 [1339192]	8.09 [10.07]
Nouvelle-Aquitaine, France (Carrat)	May 4 to June 23 (90% of tests were performed May 4 to May 24)	1765; 29	65; 65	IgG	1.64; 1.64	Age, sex, socio-professional category	303 [409]	1407119 [1465885]	1.09 [1.35]
Hungary (Merkely)	May 1 to May 16	1454; 9	70; 70	IgG	0.75; 0.62	"Several area-, dwelling unit-, and individual-level auxiliary information", region, sex, age	248 [348]	1198425 [1249016]	2.28 [3.07]
Iceland (Gudbjartsson)	May 5 to June 12 (healthcare sample)	NA; NA	70; 70	IgG/IgM/IgA	0.47; NA	Region, sex, age	5 [7]	32787 [34865]	3.12 [4.23]
India (Murhekar)	August 19 to September 20	2768; 291	61; 61	IgG	6.2; 10.51	Sampling district, test performance	33655 [41386]	125239751 [125325806]	0.36 [0.44]
Tamil Nadu, India (Malani)	October 19 to November 30	1568; NA	70; 70	IgG	25.2; NA	Age, gender, test performance, district	3518 [4326]	4324278 [4328822]	0.27 [0.33]
Italy (Istat)	May 25 to July 15	NA; NA	70; 70	IgG	2.5; NA	Region, municipal type, gender, age	19341 [29722]	10137127 [10400756]	6.31 [9.45]

						group, employment status, municipal prevalence, percentage difference in municipal mortality rates compared to the same period of the previous year			
Qatar (Abu-Raddad)	May 12 to July 12 (median day June 28)	1809; 162	70; 70	IgG	12.95; 8.96	Sex, age, nationality	53 [65]	18166 [18247]	1.85 [2.25]
Spain (Ministerio de Sanidad / ISCIII)	November 16 to November 29	7526; NA	70; 70	IgG/IgM	6.75; NA	Province, sex, age, income	23335 [41681]	6512456 [6823002]	4.83 [7.86]
United Kingdom (UK Biobank)	May 27 to Aug 14 (however monthly repeated sampling)	3956; NA	65; 70	Missing/Unclear	NA; 6.1	None	25678 [49669]	11917570 [12374961]	3.53 [6.58]
England, United Kingdom (Ward)	June 20 to July 13	21953; 801	70; 65	IgG	3.14; 3.65	Test performance, age, sex, region, ethnicity, deprivation	22644 [41023]	7204057 [7556976]	8.28 [13.82]
England and Wales, United Kingdom (Public Health England)	May 1 to May 30	1702; NA	70; 70	Missing/Unclear	3.2; NA	"Population-weighted unadjusted"	21063 [37838]	7665426 [8037210]	8.59 [14.03]
Greater Glasgow and Clyde, Scotland, United Kingdom	March 16 to May 24	2771; NA	70; 65	IgG	5.25; 8.23	Test performance, population-level dynamics, sex, age, care type, week of sample collection	295 [627]	188673 [195952]	2.46 [4.85]

(Hughes)									
USA (Anand)	July (>80% in first 2 weeks)	13659; 1043	65; 65	IgG/IgM/IgA	7.84; 7.64	Age, sex, geographical region, race and ethnicity	51128 [111774]	52441191 [54058263]	1.24 [2.56]
USA (Kalish)	April 1 to August 2020 (>88% between May 10 and July 31)	1273; 46	65; 70	IgG/IgM/IgA	3.5; 3.61	Region, age, sex, race, ethnicity, urban/rural, children, education, homeowner, employment, health insurance, health-related questions, test performance	46571 [103862]	52441191 [54058263]	1.86 [5.49]

France (INSERM): The total number of deaths in elderly is derived from their Tableau 3 (deaths occurring in hospital) and Tableau 2 (deaths in care homes). France (Carrat, Ile-de-France): see Appendix Table 2 for our calculation of deaths in elderly and community-dwelling elderly. Iceland (Gudbjartsson): Estimate is based on seroprevalence and PCR testing; persons previously diagnosed with COVID-19 did not enroll in the study. USA (Kalish): Excluded previously COVID-19-diagnosed persons from participating, why we added cases in community-dwelling elderly up to the study midpoint to the number of infected. UK (Hughes): COVID-19 death statistics for nursing home residents did not include deaths occurring in hospital, and so was corrected with a factor of 1.225 (the median of the ratio of deaths in nursing home residents / deaths occurring in nursing homes, in the European countries with such data in Comas-Herrera et al, International Long-Term Care Policy Network report, October 14). NA: Not applicable (missing).

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The mechanisms of action of Ivermectin against SARS-CoV-2 ...

Direct action of **Ivermectin** on **SARS**-CoV-2. Level 1: Action on **SARS**-CoV-2 cell entry. A study by Lehrer S et al observed that **Ivermectin** docked in the region of leucine 91 of the **SARS**-CoV-2 spike protein and histidine 378 of the host cell ACE-2 receptor blocking its entry into the host cell . In yet another study by Eweas et al., potential ...

https://pubmed.ncbi.nlm.nih.gov › 33278625

A five-day course of ivermectin for the treatment of COVID ...

Ivermectin, a US Food and Drug Administration-approved anti-parasitic agent, was found to inhibit severe acute respiratory syndrome coronavirus 2 (**SARS**-CoV-2) replication in vitro. A randomized, double-blind, placebo-controlled trial was conducted to determine the rapidity of viral clearance and safety of **ivermectin** among adult **SARS**-CoV-2 patients.

https://pubmed.ncbi.nlm.nih.gov › 33592050

Role of ivermectin in the prevention of SARS-CoV-2 ...

Two-dose **ivermectin** prophylaxis (AOR 0.27, 95% CI, 0.15-0.51) was associated with a 73% reduction of **SARS**-CoV-2 infection among healthcare workers for the following month. Those involved in physical activity (AOR 3.06 95% CI, 1.18-7.93) for more than an hour/day were more likely to contract **SARS**-CoV-2 infection.

https://www.ncbi.nlm.nih.gov › pmc › articles › PMC8607737

Prospective mode of action of Ivermectin: SARS-CoV-2

2. Mechanism of action for IVM. The efficacy of IVM in the treatment of broad spectrum of parasitic infections as well as other viruses and bacteria is well established, but the mode of action is less clear (Table 1) [].IVM at nanomolar concentrations affects nematode motility, feeding, and reproduction and acts via ligand-gated chloride channels, specifically those gated by glutamate [].

https://pubmed.ncbi.nlm.nih.gov › 32473642

Ivermectin, a new candidate therapeutic against SARS-CoV-2 ...

Ivermectin, a new candidate therapeutic against **SARS**-CoV-2/COVID-19. **Ivermectin**, a new candidate therapeutic against **SARS**-CoV-2/COVID-19. **Ivermectin**, a new candidate therapeutic against **SARS**-CoV-2/COVID-19 Ann Clin Microbiol Antimicrob. 2020 May 30;19(1):23. doi: 10.1186/s12941-020-00368-w. ...

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The FDA-approved drug ivermectin inhibits the replication ...

We report here that **Ivermectin**, an FDA-approved anti-parasitic previously shown to have broad-spectrum anti-viral activity in vitro, is an inhibitor of the causative virus (**SARS**-CoV-2), with a single addition to Vero-hSLAM cells 2 h post infection with **SARS**-CoV-2 able to effect

ivermectin sars cov2

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The binding energy of **ivermectin** to the spike-ACE2 complex was -18 kcal/mol and binding constant was 5.8 e-08. Conclusion: The **ivermectin** docking we identified may interfere with the attachment of the spike to the human cell membrane. Clinical trials now underway should determine whether **ivermectin** is an effective treatment for **SARS-Cov2** infection.

https://www.ncbi.nlm.nih.gov › pmc › articles › PMC7996102

Exploring the binding efficacy of ivermectin against the ...

Aim: COVID-19 is currently the biggest threat to mankind. Recently, **ivermectin** (a US FDA-approved antiparasitic drug) has been explored as an anti-**SARS**-CoV-2 agent. Herein, we have studied the possible mechanism of action of **ivermectin** using in silico approaches.Materials & methods: Interaction of **ivermectin** against the key proteins involved in **SARS**-CoV-2 pathogenesis were investigated through ...

https://covid19criticalcare.com › wp-content › uploads › 2021 › 08 › SUMMARY-OF-THE-...

PDF Summary of the Evidence for Ivermectin in COVID-19 ...

Ivermectin is an anti-parasite medicine whose discovery won the Nobel Prize in 2015 for its impacts in ridding large parts of the globe of parasitic diseases via the distribution of over 3.7 billion doses within public health campaigns since 1987. ... Further, the IC-50 against **SARS-CoV2** in lung and

https://www.ncbi.nlm.nih.gov › pmc › articles › PMC7146719

Hydroxychloroquine and ivermectin: A synergistic ...

To the Editor: Severe acute respiratory syndrome coronavirus 2 (**SARS**-CoV-2) infection has spread all over the world. While awaiting a vaccine, we need effective drugs to treat or, even better, prevent coronavirus disease-19 (COVID-19). Two drugs classically used by dermatologists are being examined in the fight against COVID-19: hydroxychloroquine (HCQ), and, very recently, **ivermectin**.

More Results

Virol J. 2005 Aug 22;2:69. doi: 10.1186/1743-422X-2-69.

Chloroquine is a potent inhibitor of SARS coronavirus infection and spread

Martin J Vincent [1], Eric Bergeron, Suzanne Benjannet, Bobbie R Erickson, Pierre E Rollin, Thomas G Ksiazek, Nabil G Seidah, Stuart T Nichol

Affiliations
PMID: 16115318 PMCID: PMC1232869 DOI: 10.1186/1743-422X-2-69
Free PMC article

Abstract

Background: Severe acute respiratory syndrome (SARS) is caused by a newly discovered coronavirus (SARS-CoV). No effective prophylactic or post-exposure therapy is currently available.

Results: We report, however, that chloroquine has strong antiviral effects on SARS-CoV infection of primate cells. These inhibitory effects are observed when the cells are treated with the drug either before or after exposure to the virus, suggesting both prophylactic and therapeutic advantage. In addition to the well-known functions of chloroquine such as elevations of endosomal pH, the drug appears to interfere with terminal glycosylation of the cellular receptor, angiotensin-converting enzyme 2. This may negatively influence the virus-receptor binding and abrogate the infection, with further ramifications by the elevation of vesicular pH, resulting in the inhibition of infection and spread of SARS CoV at clinically admissible concentrations.

Conclusion: Chloroquine is effective in preventing the spread of SARS CoV in cell culture. Favorable inhibition of virus spread was observed when the cells were either treated with chloroquine prior to or after SARS CoV infection. In addition, the indirect immunofluorescence assay described herein represents a simple and rapid method for screening SARS-CoV antiviral compounds.

Figures

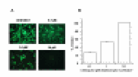


Figure 1 Prophylactic effect of chloroquine ....

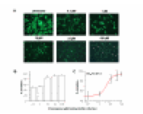


Figure 2 Post-infection chloroquine treatment reduces SARS-CoV...

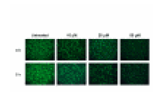


Figure 3 Timed post-infection treatment with chloroquine...



Figure 4 NH $_4$ Cl inhibits SARS-CoV...

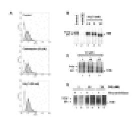


Figure 5 Effect of lysomotropic agents on...

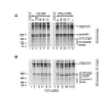


Figure 6 Effects of NH $_4$ Cl...

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MedGen
PubChem Compound
PubChem Compound (MeSH Keyword)
PubChem Substance

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Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections

Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon

doi: https://doi.org/10.1101/2021.08.24.21262415

Abstract

Background Reports of waning vaccine-induced immunity against COVID-19 have begun to surface. With that, the comparable long-term protection conferred by previous infection with SARS-CoV-2 remains unclear.

Methods We conducted a retrospective observational study comparing three groups: (1)SARS-CoV-2-naïve individuals who received a two-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine, (2)previously infected individuals who have not been vaccinated, and (3)previously infected *and* single dose vaccinated individuals. Three multivariate logistic regression models were applied. In all models we evaluated four outcomes: SARS-CoV-2 infection, symptomatic disease, COVID-19-related hospitalization and death. The follow-up period of June 1 to August 14, 2021, when the Delta variant was dominant in Israel.

breakthrough infection with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant (*P*<0.001) for symptomatic disease as well. When allowing the infection to occur at any time before vaccination (from March 2020 to February 2021), evidence of waning natural immunity was demonstrated, though SARS-CoV-2 naïve vaccinees had a 5.96-fold (95% CI, 4.85 to 7.33) increased risk for breakthrough infection and a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic disease. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalizations compared to those that were previously infected.

Conclusions This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. Individuals who were both previously infected with SARS-CoV-2 and given a single dose of the vaccine gained additional protection against the Delta variant.

Competing Interest Statement

The authors have declared no competing interest.

Funding Statement

There was no external funding for the project.

Author Declarations

I confirm all relevant ethical guidelines have been followed, and any necessary IRB and/or ethics committee approvals have been obtained.

Yes

The details of the IRB/oversight body that provided approval or exemption for the research described are given below:

This study was approved by the MHS (Maccabi Healthcare Services) Institutional Review Board (IRB). Due to the retrospective design of the study, informed consent was waived by the IRB, and all identifying details of the participants were removed before computational analysis.

All necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived.

I understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).

Yes

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

Yes

Footnotes

- The authors declare they have no conflict of interest.
- **Funding:** There was no external funding for the project.

Paper in collection COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

Preprint discussion sites covering this article:

2019 Novel Coronavirus Research Compendium, 25 Aug 2021

PUBPEER PubPeer, 30 Aug 2021

Blog posts linking to this article:

ZERO ANTHROPOLOGY, 01 Dec 2021

“Two weeks to flatten the curve,” is what we heard across Canada1 just after March 11, 2020, when the World Health Organization…

Booster Shots - latimes.com, 27 Nov 2021

In people who got a booster shot, levels of neutralizing antibodies exceeded the peak that followed two doses of COVID-19…

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17	175[a]
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
	Unknown	6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

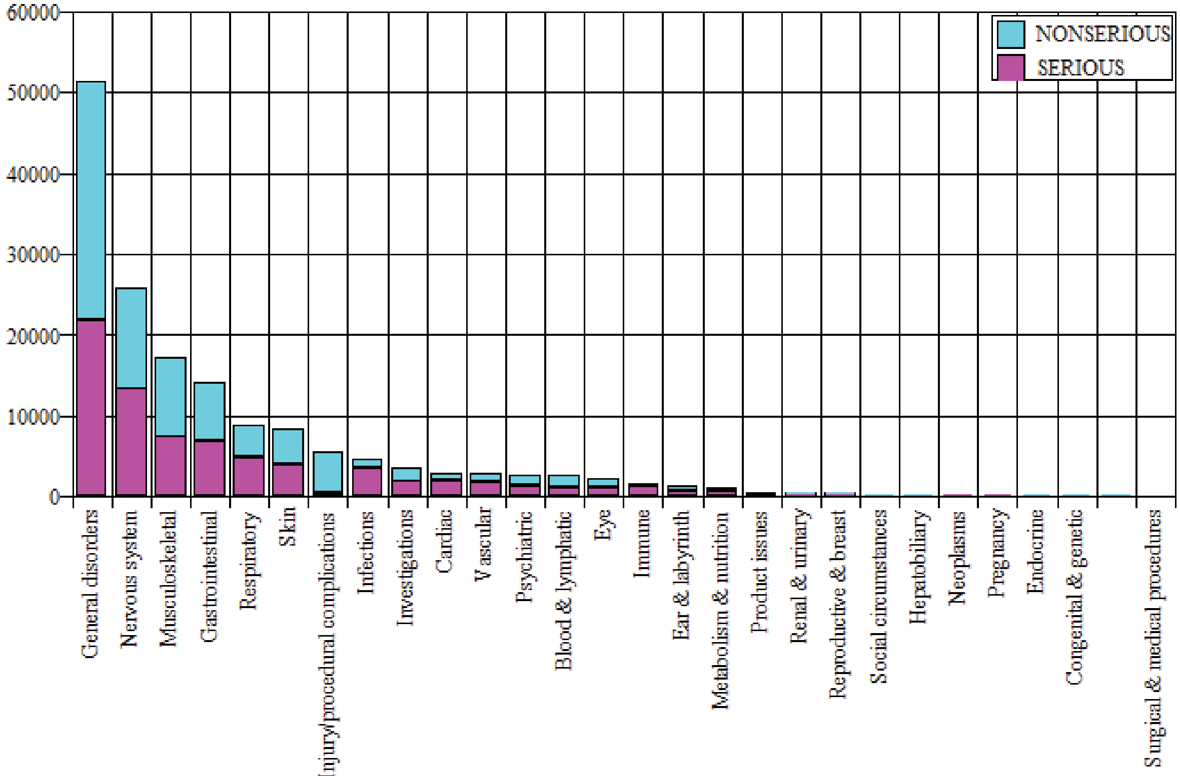


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

MedDRA SOC	MedDRA PT	Cumulatively Through 28 February 2021 AEs (AERP%) N = 42086
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 2. Events Reported in ≥2% Cases

MedDRA SOC	MedDRA PT	Cumulatively Through 28 February 2021 AEs (AERP%) N = 42086
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

Table 4. Important Identified Risk

Topic	Description
Important Identified Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)** **Total Number of Cases in the Reporting Period (N=42086)**
Anaphylaxis	Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below: Brighton Collaboration Level: Number of cases BC 1: 290 BC 2: 311 BC 3: 10 BC 4: 391 BC 5: 831 *Total*: 1833 Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis. There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4: Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries. Relevant event seriousness: Serious (2341), Non-Serious (617); Gender: Females (876), Males (106), Unknown (20); Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years); Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754); Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64). Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.

Inner table (within Anaphylaxis description):

Brighton Collaboration Level	Number of cases
BC 1	290
BC 2	311
BC 3	10
BC 4	391
BC 5	831
Total	1833

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)** **Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)** **Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

Table 6. Description of Missing Information

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><th>Missing Information</th><th>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)</th></tr>
<tr><td></td><td>• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each).
Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.</td></tr>
<tr><td>Use in Paediatric Individuals <12 Years of Age</td><td><u>Paediatric individuals <12 years of age</u>
• Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age;
• Country of incidence: UK (29), US (3), Germany and Andorra (1 each);
• Cases Seriousness: Serious (24), Non-Serious (10);
• Gender: Females (25), Males (7), Unknown (2);
• Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0;
• Case outcome: resolved/resolving (16), not resolved (13), and unknown (5).
• Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each).

Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.</td></tr>
<tr><td>Vaccine Effectiveness</td><td>Company conventions for coding cases indicative of lack of efficacy:

The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below:
• PT “Vaccination failure” is coded when ALL of the following criteria are met:
    o The subject has received the series of two doses per the dosing regimen in local labeling.
    o At least 7 days have elapsed since the second dose of vaccine has been administered.
    o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests).
• PT “Drug ineffective” is coded when either of the following applies:
    o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., “the vaccine did not work”, “I got COVID-19”.
    o It is unknown:
        ▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling;
        ▪ How many days have passed since the first dose (including unspecified number of days like” a few days”, “some days”, etc.);
        ▪ If 7 days have passed since the second dose;
    o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose.

Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete.

Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:</td></tr>
</table>

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)** **Total Number of Cases in the Reporting Period (N=42086)**

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code “Drug ineffective”	Code “Vaccination failure”
Scenario Not considered LOE	Scenario considered LOE as “Drug ineffective”	Scenario considered LOE as “Vaccination failure”

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

Drug ineffective cases (1649)

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)** **Total Number of Cases in the Reporting Period (N=42086)**
	2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness. ***Vaccination failure cases (16)*** • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: o Within 7 and 13 days: 8 subjects; o Within 15 and 29 days: 6 subjects. COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases. Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
Anaphylactic Reactions *Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria*	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs *Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*	• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
	• Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Dermatological AESIs *Search criteria: PT Chillblains; Erythema multiforme*	• Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Facial Paralysis *Search criteria: PTs Facial paralysis, Facial paresis*	• Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each); • Number of relevant events[k]: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Musculoskeletal AESIs *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial*[n]*; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis*	• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
	• Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Other AESIs *Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient*	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation[b]** **Total Number of Cases (N=42086)**
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*
Renal AESIs *Search criteria: PTs Acute kidney injury; Renal failure.*	• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Stroke *Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents*	• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

Medication error case outcomes:

- Fatal (7)[3],
- Recovered/recovering (354, of which 4 are serious),
- Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

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Remdesivir and Acute Renal Failure: A Potential Safety Signal From Disproportionality Analysis of the WHO Safety Database

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Abstract

Remdesivir is approved for emergency use by the US Food and Drug Administration (FDA) and authorized conditionally by the European Medicines Agency (EMA) for patients with coronavirus disease 2019 (COVID-19). Its benefit-risk ratio is still being explored because data in the field are rather scant. A decrease of the creatinine clearance associated with remdesivir has been inconstantly reported in clinical trials with unclear relevance. Despite these uncertainties, we searched for a potential signal of acute renal failure (ARF) in pharmacovigilance postmarketing data. An analysis of the international pharmacovigilance postmarketing databases (VigiBase) of the World Health Organization (WHO) was performed, using two disproportionality methods. Reporting odds ratio (ROR) compared the number of ARF cases reported with remdesivir, with those reported with other drugs prescribed in comparable situations of COVID-19 (hydroxychloroquine, tocilizumab, and lopinavir/ritonavir). The combination of the terms "acute renal failure" and "remdesivir" yielded a statistically significant disproportionality signal with 138 observed cases instead of the 9 expected. ROR of ARF with remdesivir was 20-fold (20.3; confidence interval 0.95 [15.7-26.3], $P < 0.0001$]) that of comparative drugs. Based on ARF cases reported in VigiBase, and despite the caveats inherent to COVID-19 circumstances, we detected a statistically significant pharmacovigilance signal of nephrotoxicity associated with remdesivir, deserving a thorough qualitative assessment of all available data. Meanwhile, as recommended in its Summary of Product Characteristics, assessment of patients with COVID-19 renal function should prevail before and during treatment with remdesivir in COVID-19.

> COVID-19 drug treatment

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Shedding of Infectious SARS-CoV-2 Despite Vaccination

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Abstract

The SARS-CoV-2 Delta variant might cause high viral loads, is highly transmissible, and contains mutations that confer partial immune escape [1,2]. Outbreak investigations suggest that vaccinated persons can spread Delta [3,4]. We compared RT-PCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin 29 June through 31 July 2021 and tested with a qualitative assay by a single contract laboratory. Specimens came from residents of 36 counties, most in southern and southeastern Wisconsin, and 81% of cases were not associated with an outbreak. During this time, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and state immunization records (**Supplemental Figure 1**).

Main text

We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%; **Figure 1A**) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people (**Figure 1B**).

Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing (**Figure 1C**). Ct values <25 were detected in 7 of 24 unvaccinated (29%; CI: 13-51%) and 9 of 11 fully vaccinated asymptomatic individuals (82%; CI: 48-97%), and 158 of 232 unvaccinated (68%, CI: 62-74%) and 156 of 225 fully vaccinated (69%; CI: 63-75%) symptomatic individuals. Time from symptom onset to testing did not vary by vaccination status (p=0.40; **Supplemental Figure 2**). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although few asymptomatic individuals were sampled, these results indicate that even asymptomatic, fully vaccinated people might shed infectious virus.

Combined with other studies [2–5], these data indicate that vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-

2 is frequently found even in vaccinated persons when specimen Ct values are low. The inclusion of viruses from Pango lineages B.1.617.2, AY.2, and AY.3, and multiple counties without a linking outbreak, indicate that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent with transmissibility in fully vaccinated individuals across a range of settings. Vaccinated and unvaccinated persons should get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19. Continued adherence to non-pharmaceutical interventions during periods of high community transmission to mitigate spread of COVID-19 remain important for both vaccinated and unvaccinated individuals.

Figure

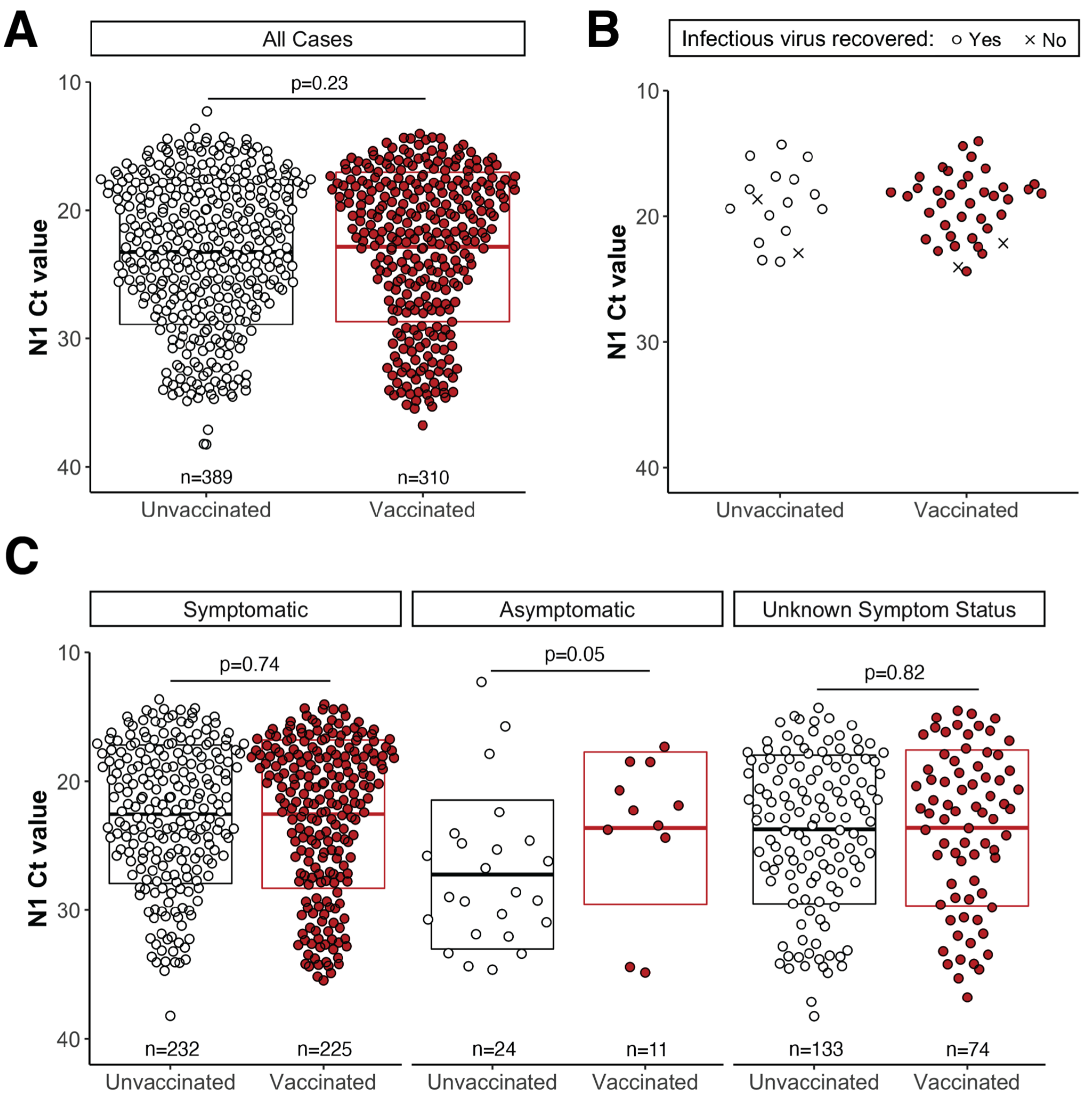


Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values and shed infectious virus. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. RT-PCR was performed by Exact Sciences Corporation, responsible for over 10% of all PCR tests in Wisconsin during this period, using a qualitative diagnostic assay targeting the SARS-CoV-2 N gene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized for emergency use by FDA (https://www.fda.gov/media/138328/download). **B.** Infectiousness was determined for a subset of N1 Ct-matched specimens with Ct <25 by inoculation onto Vero E6 TMPRSS2 cells and determining presence of cytopathic effects (CPE) after 5 days in culture. Specimens were selected by N1 Ct-matching between fully vaccinated and not fully vaccinated persons, then specimens from persons with unknown vaccination status were excluded from the analysis. Circles indicate presence of CPE; 'X' indicates no CPE detected. **C.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic or asymptomatic, or those whose symptom status was not determined, at the time of testing. In **A** and **C**,

boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

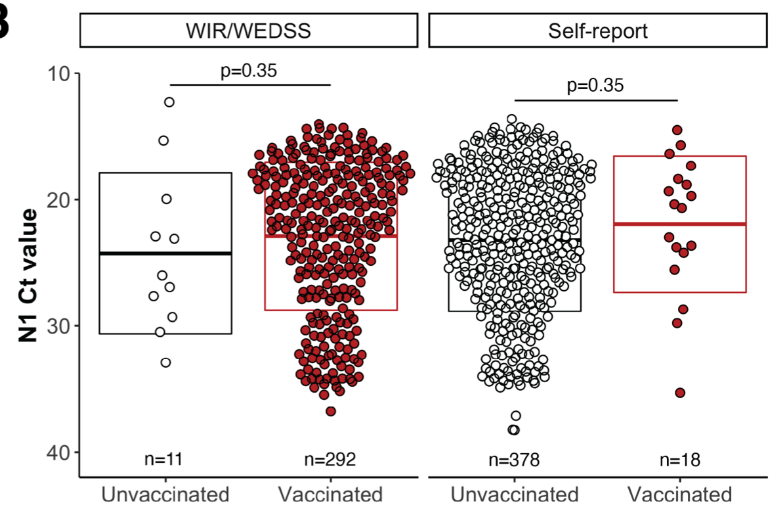
Supplemental materials

Supplemental figure 1

A

		Vaccinated per self-report: Yes	Vaccinated per self-report: No
Vaccinated per WIR or WEDSS	Yes	124	33
	No	0	8

B



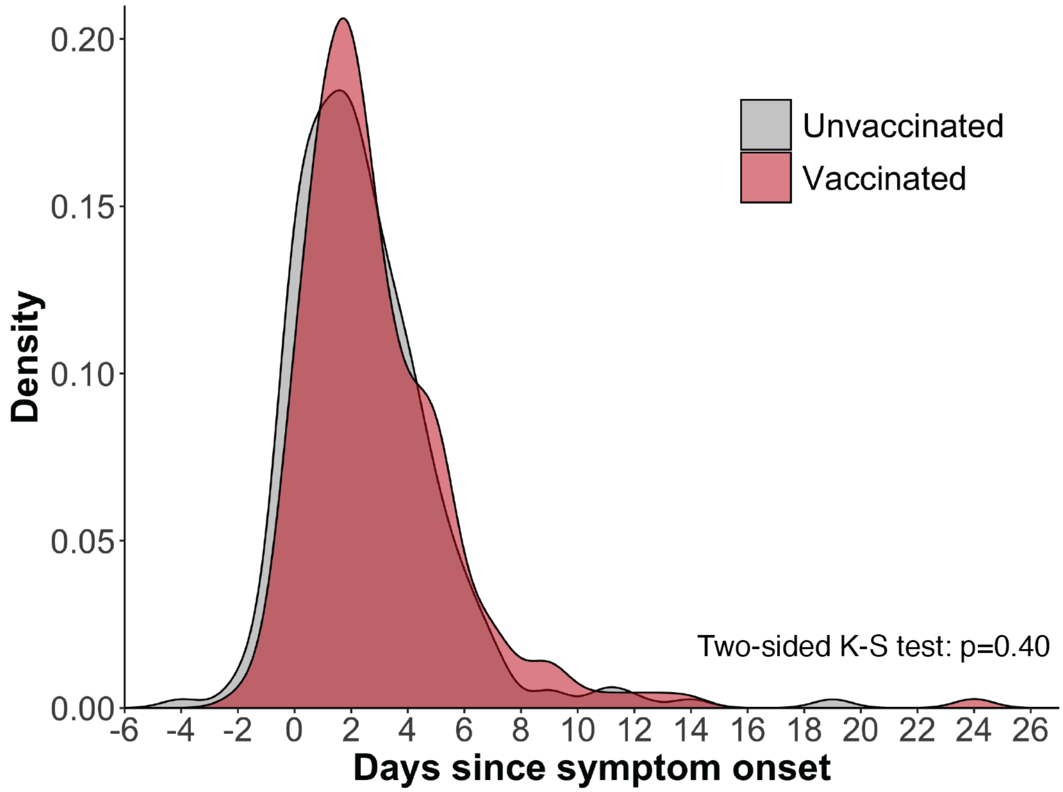
Supplemental figure 1. Concordance between self-reported vaccination status and the Wisconsin Immunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For all individuals, vaccination status was determined using WIR/WEDSS electronic registries when data were available. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS data indicated receipt of a first SARS-CoV-2 vaccine dose after the test date.

Individuals were considered fully vaccinated based on WIR/WEDSS data if the registries indicated receipt of a final vaccine dose at least 14 days prior to testing. For individuals whose vaccination status could not be verified in WIR/WEDSS, self-reported data collected at the time of testing were used. Individuals were considered unvaccinated based on self-report only if there was an explicit declaration of unvaccinated status in the self-reported data. Individuals were considered fully vaccinated based on self-report if they fulfilled all of the following criteria: (1) indicated that they had received a COVID vaccine prior to testing; (2) indicated that they did not require another vaccine dose; and (3) reported a date of last vaccine dose that was at least 14 days prior to testing.

Specimens lacking data on vaccination status were excluded from the study. Specimens from partially vaccinated individuals (incomplete vaccine series, or <14 days post-final dose) were also excluded. Fully vaccinated status was determined by WIR/WEDSS for 292 specimens and by self-reported data for 18. Unvaccinated status was determined by WIR/WEDSS for 11 and by self-reported data by 378. **A.** Of the 699 specimens with vaccination status available from at least one source, 165 specimens had data available from both sources. For self-reporting, under-reporting of full vaccination status (33/157) was more common than over-reporting (0/124). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals whose vaccination status was determined by WIR/WEDDS or by self-reported data. Boxplots represent mean N1 Ct values +/- one standard

deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental figure 2



Supplemental figure 2. Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=263 unvaccinated cases and n=232 vaccinated cases.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(l)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

The opinions expressed by authors contributing to this journal do not necessarily reflect the opinions of the Centers for Disease Control and Prevention or the institutions with which the authors are affiliated.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, culture status, and days from symptom onset to testing for each specimen.

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COVID-19

- Get the latest public health information from CDC
- Get the latest research information from NIH | Español
- NIH staff guidance on coronavirus (NIH Only)

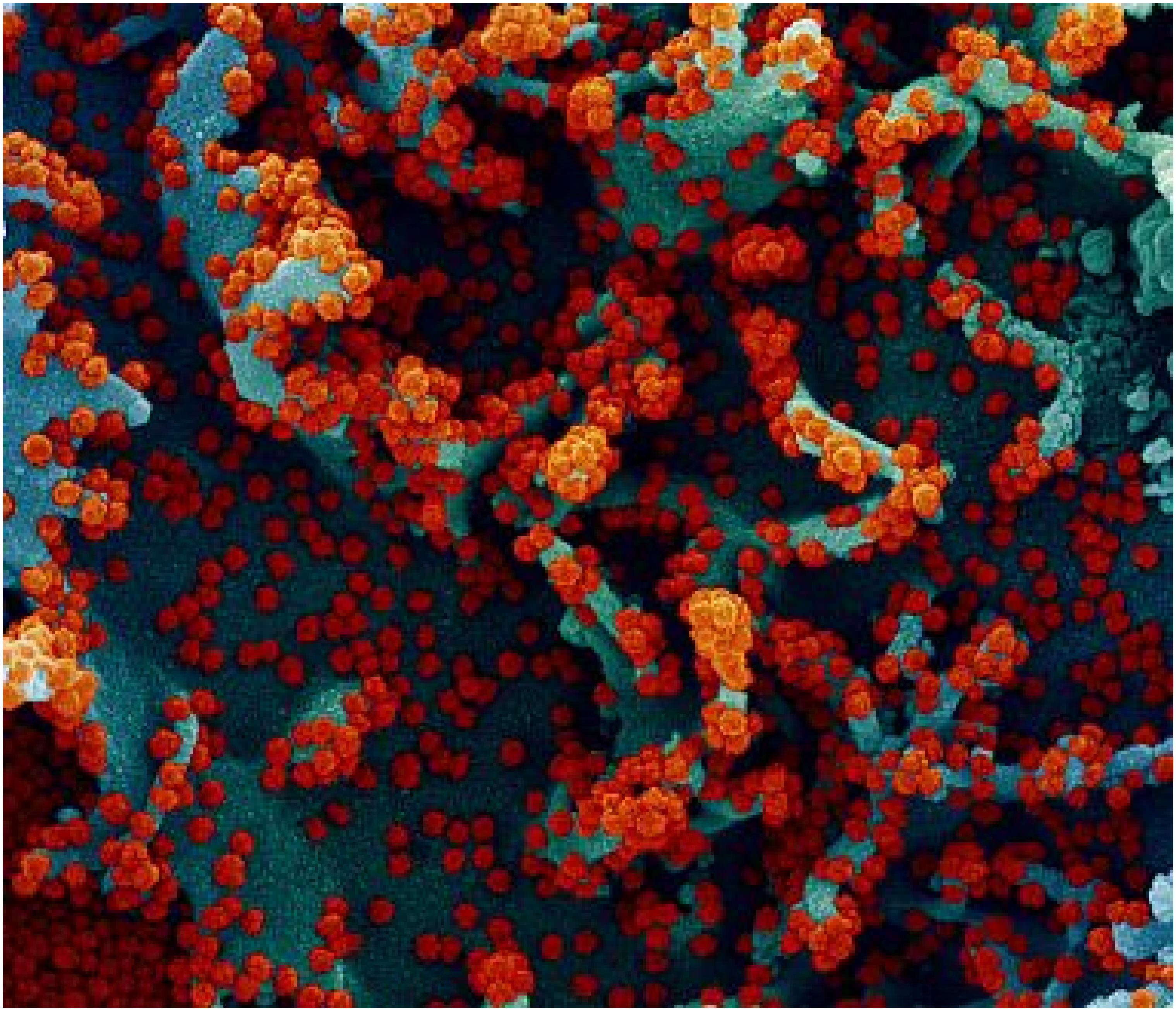
NIH RESEARCH MATTERS

January 26, 2021

Lasting immunity found after recovery from COVID-19

At a Glance

- The immune systems of more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection.
- The results provide hope that people receiving SARS-CoV-2 vaccines will develop similar lasting immune memories after vaccination.



Colorized scanning electron micrograph of a cell, isolated from a patient sample, that is heavily infected with SARS-CoV-2 virus particles (red). *NIAID Integrated Research Facility, Fort Detrick, Maryland*

After people recover from infection with a virus, the immune system retains a memory of it. Immune cells and proteins that circulate in the body can recognize and kill the pathogen if it's encountered again, protecting against disease and reducing illness severity.

This long-term immune protection involves several components. Antibodies—proteins that circulate in the blood—recognize foreign substances like viruses and neutralize them. Different types of T cells help recognize and kill pathogens. B cells make new antibodies when the body needs them.

All of these immune-system components have been found in people who recover from SARS-CoV-2, the virus that causes COVID-19. But the details of this immune response and how long it lasts after infection have been unclear. Scattered reports of reinfection with SARS-CoV-2 have raised concerns that the immune response to the virus might not be durable.

To better understand immune memory of SARS-CoV-2, researchers led by Drs. Daniela Weiskopf, Alessandro Sette, and Shane Crotty from the La Jolla Institute for Immunology analyzed immune cells and antibodies from almost 200 people who had been exposed to SARS-CoV-2

and recovered.

Time since infection ranged from six days after symptom onset to eight months later. More than 40 participants had been recovered for more than six months before the study began. About 50 people provided blood samples at more than one time after infection.

The research was funded in part by NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI). Results were published on January 6, 2021, in *Science*.

The researchers found durable immune responses in the majority of people studied. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset. As seen in previous studies, the number of antibodies ranged widely between individuals. But, promisingly, their levels remained fairly stable over time, declining only modestly at 6 to 8 months after infection.

Virus-specific B cells increased over time. People had more memory B cells six months after symptom onset than at one month afterwards. Although the number of these cells appeared to reach a plateau after a few months, levels didn't decline over the period studied.

Levels of T cells for the virus also remained high after infection. Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus. These cells help coordinate the immune response. About half the participants had CD8+ T cells, which kill cells that are infected by the virus.

As with antibodies, the numbers of different immune cell types varied substantially between individuals. Neither gender nor differences in disease severity could account for this variability. However, 95% of the people had at least 3 out of 5 immune-system components that could recognize SARS-CoV-2 up to 8 months after infection.

"Several months ago, our studies showed that natural infection induced a strong response, and this study now shows that the responses last," Weiskopf says. "We are hopeful that a similar pattern of responses lasting over time will also emerge for the vaccine-induced responses."

—by Sharon Reynolds

Related Links

- Experimental Coronavirus Vaccine Highly Effective (https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective)
- Antibodies and T Cells Protect Against SARS-CoV-2 (https://www.nih.gov/news-events/nih-research-matters/antibodies-t-cells-protect-against-sars-cov-2)
- Immune Cells for Common Cold May Recognize SARS-CoV-2 (https://www.nih.gov/news-events/nih-research-matters/immune-cells-common-cold-may-recognize-sars-cov-2)
- Potent Neutralizing Antibodies Target New Regions of Coronavirus Spike (https://www.nih.gov/news-events/nih-research-matters/potent-neutralizing-antibodies-target-new-regions-coronavirus-spike)
- Potent Antibodies Found in People Recovered from COVID-19 (https://www.nih.gov/news-events/nih-research-matters/potent-antibodies-found-people-recovered-covid-19)
- Novel Coronavirus Structure Reveals Targets for Vaccines and Treatments (https://www.nih.gov/news-events/nih-research-matters/novel-coronavirus-structure-reveals-targets-vaccines-treatments)
- Coronavirus (COVID-19) (https://covid19.nih.gov/)
- Coronavirus Prevention Network (https://www.coronaviruspreventionnetwork.org/)

- Coronavirus (COVID-19) (https://www.coronavirus.gov/)

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Funding: NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI); La Jolla Institute for Immunology; John and Mary Tu Foundation; Bill and Melinda Gates Foundation; Mastercard; Wellcome; Emergent Ventures; Collaborative Influenza Vaccine Innovation Centers; JPB Foundation; Cohen Foundation; Open Philanthropy Project.

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Innova Medical Group Recalls Unauthorized SARS-CoV-2 Antigen Rapid Qualitative Test with Risk of False Test Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- **Innova SARS-CoV-2 Antigen Rapid Qualitative Test** (also distributed under the names Innova COVID-19 Self-Test Kit (3T Configuration), Innova SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration), and Innova SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration))
- **Lot codes:**
  - **25T (25 tests per box) -** U2101750, U2101751, X2006004, X2008001, X2008010, X2009002, X2009004, X2009013, X2009016, X2010004, X2010010, X2011005, X2011006, X2011007, X2011008, X2011009, X2011012, X2011013, X2011015, X2011016, X2011017, X2011025, X2011051, X2011052, X2012001, X2012002, X2012004, X2012005, X2012008, X2101002, X2101004, X2101014, X2101031, X2101038
  - **3T (3 tests per box) -** U2102003, X2012310
  - **7T (7 tests per box) -** U2101748, U2102001, U2102002, X2012711, X2103792
- **Manufacturing Dates:** September 1, 2020 to March 3, 2021
- **Distribution Dates:** November 2, 2020 to March 22, 2021
- **Devices Recalled in the U.S.:** At least 77,339
- **Date Initiated by Firm:** March 24, 2021

Device Description

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test claimed to determine if a person has an active COVID-19 infection. The test used a nasal swab sample and test strip to detect specific proteins, called antigens, from the SARS-CoV-2 virus. If the nasal sample had SARS-CoV-2 antigens, a colored test line should have appeared on the test strip, indicating that the person

should not have appeared on the test strip. The test has not been authorized, cleared, or approved by FDA for commercial distribution in the United States.

Reason for Recall

Innova Medical Group is recalling its SARS-CoV-2 Antigen Rapid Qualitative Test. Labeling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during the clinical studies of the tests. The performance characteristics of the test have not been adequately established, presenting a risk of false results.

- **False-negative results** may lead to delayed diagnosis or inappropriate treatment of SARS-CoV-2, which may cause patient harm including serious illness and death. False-negative results can also lead to further spread of the SARS-CoV-2 virus, including when presumed negative patients are grouped into cohorts in health care, long-term care, and other facilities based on false test results.
- **False-positive results** could lead to a delay in the correct diagnosis and the initiation of an appropriate treatment for the actual cause of patient illness, which could be another life-threatening disease that is not SARS-CoV-2. False-positive results could also lead to further spread of the SARS-CoV-2 virus when presumed positive patients are grouped into cohorts based on false test results.

Who May Be Affected

- People who were tested using these devices
- Health care providers who may have access to and use these tests or whose patients have used these tests
- Organizers of large testing programs, such as on college campuses, who may be using and distributing these tests for diagnostic use

What to Do

On April 23, 2021, Innova Medical Group sent all affected device users an Urgent Medical Device Recall letter. The letter provided the following information:

- Do not use these tests to screen for or diagnose COVID-19.
- Identify and remove all affected tests from inventory.
- Either destroy the tests by placing them in the trash or return the tests using the FedEx return label that was included with the letter Innova sent to its customers.

destroyed or returned tests.

The FDA also recommends:

- **Test users and caregivers:** Talk to your health care provider if you think you were tested with the Innova SARS-CoV-2 Antigen Rapid Qualitative Test and you have concerns about your test results.
- **Health care providers:** If the test was given less than two weeks ago, consider retesting your patients using a different SARS-CoV-2 diagnostic test if you suspect an inaccurate result. If testing was performed more than two weeks ago and there is no reason to suspect current SARS-CoV-2 infection, it is not necessary to retest.
- **Testing program organizers:** Notify participants in your testing program to discontinue diagnostic use of these tests and to use an FDA-authorized test to continue testing. For listings of FDA-authorized tests, see:
  - FDA-Authorized Molecular Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
  - FDA-Authorized Antigen Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
- Report any problems you experience with the Innova SARS-CoV-2 Antigen Rapid Test to the FDA, including suspected false results.

For more information, please see the FDA's June 2021 safety communication, Stop Using Innova SARS-CoV-2 Antigen Rapid Qualitative Test (/medical-devices/safety-communications/stop-using-innova-medical-group-sars-cov-2-antigen-rapid-qualitative-test-fda-safety-communication).

Contact Information

Customers with questions about this recall should contact Linda Weinreb at Linda.Weinreb@innovamedgroup.com (mailto:Linda.Weinreb@innovamedgroup.com) or call 747-494-0852.

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event

Risk of False Results with the Curative SARS-Cov-2 Test for COVID-19: FDA Safety Communication

The Curative, Inc., Curative SARS-Cov-2 Assay (originally authorized as the Korvalabs, Inc. Curative-Korva SARS-Cov-2 Assay) Emergency Use Authorization was revoked at the company's request effective July 15, 2021, because the company is now using different EUA-authorized tests for the testing offered at its laboratories. The test that is the subject of this safety communication is no longer being offered and is no longer authorized for emergency use by the FDA.

Date Issued: January 4, 2021

The U.S. Food and Drug Administration (FDA) is alerting patients and health care providers of the risk of false results, particularly false negative results, with the Curative SARS-Cov-2 test. Risks to a patient of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

To reduce the risk of false negative results, it is important to perform the test in accordance with its authorization and as described in the authorized labeling, e.g., the Fact Sheet for Healthcare Providers (/media/137087/download). When the test is not performed in accordance with its authorization or as described in the authorized labeling, there is a greater risk that the results of the test may not be accurate.

Important Recommendations for Health Care Providers, Patients, and Caregivers

- Be aware of the important information regarding the use of the Curative SARS-Cov-2 test, which is described in the test's authorized labeling, including the following:
  - Collection of nasal swabs and oral fluid specimens is limited to symptomatic individuals within 14 days of COVID-19 symptom onset.
  - Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.
  - A negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

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suspect an inaccurate result was given *recently* by the Curative SARS-Cov-2 test. If testing was performed more than two weeks ago, and there is no reason to suspect current SARS-Cov-2 infection, it is not necessary to retest.

- **Patients and caregivers:** Talk to your health care provider if you think you were tested with the Curative SARS-Cov-2 test (the test name is displayed on this test's authorized Fact Sheets and, generally, the Fact Sheets must be provided with test result reports) and you have concerns about your test results.
- Report any problems you experience with the Curative SARS-Cov-2 test to the FDA, including suspected inaccurate results.

Device Description

The Curative SARS-Cov-2 Assay is a real-time RT-PCR test used to detect SARS-Cov-2, the virus that causes COVID-19. This test is authorized for prescription-only use. The test is performed by collecting a throat swab, nasopharyngeal swab, nasal swab, or oral fluid specimen from an individual suspected of COVID-19 by their health care provider. Under the Emergency Use Authorization, the specimen is then to be processed at the KorvaLabs, Inc., laboratory, and results are returned to the patient.

Consistent with the test's authorized labeling (/media/137087/download), collection of nasal swabs and oral fluid specimens is limited to individuals who have shown symptoms of COVID-19 within 14 days of onset of the symptoms. Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.

Consistent with the EUA summary (/media/137089/download), negative results for SARS-Cov-2 RNA from oral fluid specimens should be confirmed by testing of another specimen type authorized for use with this test if clinically indicated.

FDA Actions

The FDA regularly monitors the post-authorization use of tests, including reports of problems with test performance or results, and is providing this information to help educate patients, caregivers, and health care providers and reduce the risk of false results.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with a Medical Device

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including problems with test performance or results," through MedWatch (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program), the FDA Safety Information and Adverse Event Reporting program.

Generally, as specified in a test's EUA, device manufacturers and authorized laboratories must comply with applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.

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MINI-REVIEW

Ivermectin: a multifaceted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, COVID-19

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Abstract

In 2015, the Nobel Committee for Physiology or Medicine, in its only award for treatments of infectious diseases since six decades prior, honoured the discovery of ivermectin (IVM), a multifaceted drug deployed against some of the world's most devastating tropical diseases. Since March 2020, when IVM was first used against a new global scourge, COVID-19, more than 20 randomized clinical trials (RCTs) have tracked such inpatient and outpatient treatments. Six of seven meta-analyses of IVM treatment RCTs reporting in 2021 found notable reductions in COVID-19 fatalities, with a mean 31% relative risk of mortality vs. controls. During mass IVM treatments in Peru, excess deaths fell by a mean of 74% over 30 days in its ten states with the most extensive treatments. Reductions in deaths correlated with the extent of IVM distributions in all 25 states with $p < 0.002$. Sharp reductions in morbidity using IVM were also observed in two animal models, of SARS-CoV-2 and a related betacoronavirus. The indicated biological mechanism of IVM, competitive binding with SARS-CoV-2 spike protein, is likely non-epitope specific, possibly yielding full efficacy against emerging viral mutant strains.

Keywords: COVID-19, *H. pylori*, ivermectin, SARS-CoV-2, spike protein
Article published online: 3 August 2021

Corresponding author: David E. Scheim.
E-mail: dscheim@alum.mit.edu

Introduction

The 2015 Nobel prize for the discovery of ivermectin (IVM) and an antimalarial treatment was the Nobel committee's first award for treatment agents for infectious diseases since the one in 1952 for streptomycin [1]. A macrocyclic lactone of multifaceted potency [2,3], IVM as deployed worldwide since 1987 has made major inroads against two devastating tropical diseases, onchocerciasis and lymphatic filariasis [4]. During the year since IVM treatment was first applied to COVID-19, another global scourge [5], results from more than 20 randomized clinical trials (RCTs) of IVM treatment of COVID-19 have been reported [2,6,7], with inpatient and outpatient treatments of COVID-19 conducted in 25 countries [2]. A likely biological mechanism has been indicated to be competitive binding with SARS-CoV-2 spike protein sites, as reviewed [8,9].

Recently, Dr Satoshi Omura, the Nobel co-laureate for the discovery of IVM, and colleagues conducted a comprehensive review of IVM clinical activity against COVID-19, concluding that the preponderance of the evidence demonstrated major reductions in mortality and morbidity [2]. Our review of that evidence, updated with consideration of several new studies, supports the same conclusion.

Animal studies for IVM treatment of SARS-CoV-2 and a closely related betacoronavirus

A framework for the examination of clinical IVM treatment results for COVID-19 is provided by related animal studies using IVM at low human-equivalent doses. In golden hamsters that were intranasally inoculated with SARS-CoV-2, causing symptomatic COVID-19 infections, concurrent dosing with IVM significantly reduced the severity of clinical signs

https://doi.org/10.1016/j.nmni.2021.100924

($p < 0.001$). While viral load was not reduced, these improvements included one-third of the incidence of anosmia and sharp reductions in the Il-6/Il-10 ratio in lung tissue [10]. In another animal model, mice were infected with mouse hepatitis virus MHV-A59 [11], a betacoronavirus strain that does not express hemagglutinin esterase [12], like SARS-CoV-2, SARS-CoV, and MERS [8]. Whereas infected mice had severe histopathological liver damage, IVM-treated mice had half the hepatic viral load and minimal liver damage, not significantly different than that observed in uninfected controls.

RCTs for IVM treatment and prevention of COVID-19

More than 20 RCTs for IVM treatment of COVID-19 have been conducted to date, as cited above. A search of Google Scholar for meta-analyses of IVM treatment studies of COVID-19 that appeared in 2021 [13] yielded seven such studies that drew conclusions from RCTs only [6,14–19]. The relative risk (RR) of mortality with IVM treatment vs. controls as calculated in four of these meta-analyses using Cochrane analysis methodology ranged from 0.25 to 0.37, with a mean of 0.31 [6,14,15,19]. The three other meta-analyses reported odds ratios of 0.16, 0.21 and 0.33, with a mean of 0.23 [16–18]. Six of these seven meta-analyses concluded that there was a significant [6,14–16] or possible [17,18] indication of the efficacy of IVM in reducing COVID-19 mortality. One found no evidence of IVM efficacy in its first version [20], reporting an RR of 1.11 for IVM treatment vs. controls, and stuck with that finding even after changing this RR value to 0.37 and correcting switched treatment and control deaths it had misreported for one study [21] in a revised version [19]. Among the most recent and comprehensive of these seven meta-analyses reported a pooled total of 31 deaths among 1101 subjects in IVM treatment groups and 91 deaths among 1064 controls from 11 RCTs, amounting to a 67% reduction in mortality, with a statistical significance for an overall effect of $p = 0.005$ [16]. The RCT that used the largest dose of IVM, 400 μg/kg on each of days 1-4 [22], had 2 vs. 24 deaths in the treatment vs. control groups ($n = 200$ each).

An objection that had been raised earlier in 2021 to the preponderance of clinical evidence for the efficacy of IVM treatment of COVID-19 as summarized above was that none of these RCTs had been published in mainstream peer-reviewed scientific journals [23]. Closing that gap, however, was the publication in 2021 in journals from major scientific publishers of five such RCTs for COVID-19 treatment [24–28], each showing multiple clinical benefits for IVM vs. controls, most of these to statistical significance at $p < 0.002$. Also published in 2021 were three other RCTs for IVM treatment of COVID-19: one that reported briefer hospital stays for IVM treatment short of statistical significance ($p = 0.08$) [29], another that compared IVM with two other drug treatment groups but not a placebo group and found no benefit [30], and an additional study conducted in Cali, Columbia with mix-ups between treatment and placebo doses as described below.

Another objection that has been raised to the RCT evidence supporting IVM efficacy was that study populations were too small [31]. Yet, it is well known in clinical trial design that highly effective drugs will establish statistically significant results with smaller sample sizes, with larger study populations required for minimally effective drugs [32,33]. But for a drug with a more modest RR of 75%, for example, the treatment and control arms would need more than 3800 subjects each to yield the same statistical significance [33]. Although large study populations are useful to screen for adverse effects (AEs) of new drugs, IVM has been used safely in 3.7 billion doses worldwide since 1987 [2,3] and is well tolerated even at much greater doses than the standard single dose of 200 μg/kg [34,35]. It has been used in RCTs for COVID-19 treatment at cumulative doses of 1500 μg/kg [36], 1600 μg/kg [22] and 3000 μg/kg [37] over 4 or 5 days with only small percentages of mild or transient adverse effects.

Among these RCTs that established safety for high-dose IVM treatment of COVID-19 was one conducted in Cali, Columbia, with generally mild COVID-19 cases, median age 37, having only one death in the control group [36]. The study found no statistically significant symptom improvements with IVM treatment yet reported a striking anomaly: AEs distinctive for its high IVM dose, described in the study protocol as 'security parameters' for its IVM use, occurred at almost identical rates in its IVM and placebo arms. These included transient incidences of blurred vision (11.3%, 11.6%) and dizziness (35.6%, 34.3%). These indications of IVM use in controls occurred as over-the-counter sales of IVM surged in the study region during the study period (Supplementary Table 1). Further questions as to the study's treatment/control boundaries were raised by the mistaken substitution of IVM for placebo for 38 patients, discovered by the lead pharmacist a month after the fact (study, p. 3; study protocol supplement, p. 43). In addition, blinding was breached by the use of the dextrose-saline solution as the placebo for 64 control patients (IVM tastes distinctively bitter), while the composition of the replacement placebo solution was not specified [38].

Supporting the findings of IVM efficacy in COVID-19 treatment as summarized above were indications of activity against SARS-CoV-2 in prevention studies. Three RCTs evaluated the prophylactic effect of IVM administered to cohorts of 100 [22], 117 [39] and 203 [40] subjects exposed to COVID-19 patients. These studies, all using IVM in doses of at least 150 μg/kg per week, reported statistically significant reductions in COVID-19

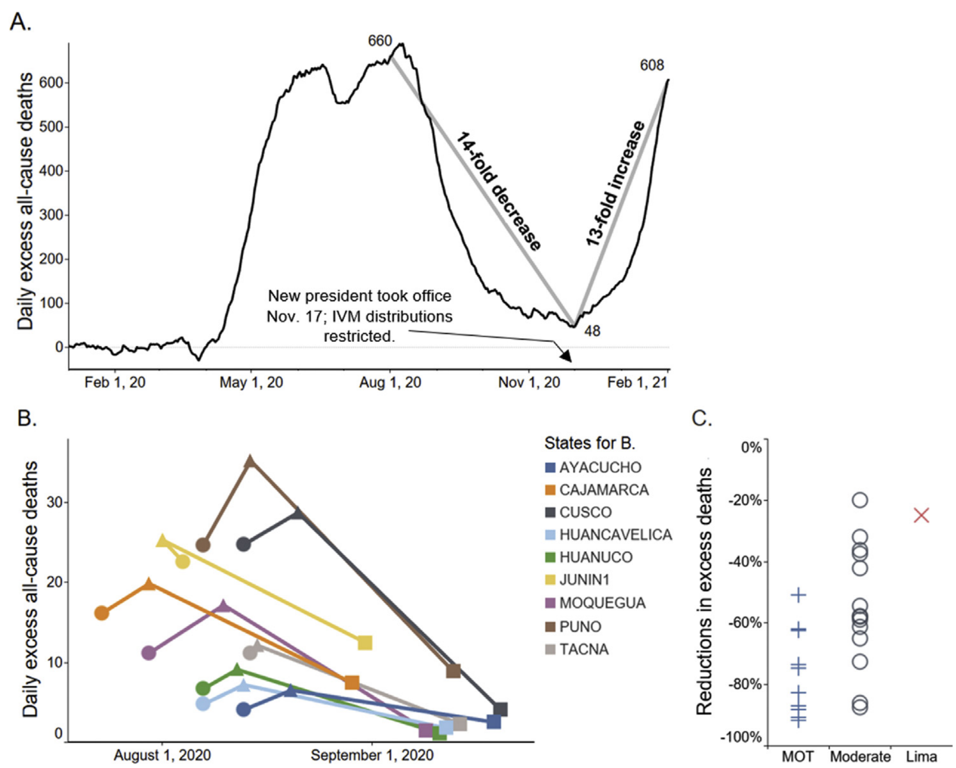


FIG. 1. A) Excess all-cause deaths (all ages), the national population of Peru. These decreased 14-fold from 1st August through 1st December 2020; then, after IVM use was restricted, increased 13-fold through 1st February. For A and B, y values are 7-day moving averages; for B and C, ages ≥60. Data are from Peru's National Death Information System (SINADEF). (B) Drops in excess deaths for all states of operation *MOT*, an army-led program of mass IVM distributions, but Pasco, which had them on three dates. ● *MOT* start date; ▲ peak deaths; ■ day of peak deaths +30 days. Junin distributed IVM through local channels 13 days before *MOT* start. (C) Reductions in excess deaths at +30 days after peak deaths for the 25 states by extent of IVM distributions: maximal-*MOT* (+), mean -74%; moderate-local distributions (○), mean -53%; and minimal-Lima (x), -25%. The absolute value of these reductions by state correlated with extent of IVM distributions with Kendall $\tau_b = 0.524$, $p < 0.002$ (Spearman rho = 0.619, $p < 0.001$). All these data are from publicly accessible Peruvian national databases, with associated frozen datasets available from the Dryad data repository [42].

incidences, with respective RRs of 20%, 26% and 13% as compared with controls, and greater reductions in incidences of moderate and severe cases. Another RCT for COVID-19 prevention administered just one dose of IVM at 12 mg (about 150 μg/kg) to 617 subjects on day one of a 42-day observation period, while three other preventative regimens were each administered daily over that period [41]. IVM at that single low dose yielded the best results of these four regimens, with highly statistically significant reductions of close to 50% in both symptomatic COVID-19 and acute respiratory symptoms vs. controls.

14-fold reductions in excess deaths with IVM use in Peru, then 13-fold increase after IVM restricted

The clinical experience of IVM treatments of COVID-19 in 25 countries extends far beyond the RCT results summarized, yet incomplete tracking and lack of control data exclude most of this for evaluation. The record of nationally authorized such treatments in Peru provides a notable exception [42]. In ten states of Peru, mass IVM treatments of COVID-19 were conducted through a broadside, army-led effort, *Mega-Operación Tayta* (*MOT*), that began on different dates in each state. In these *MOT* states, excess deaths dropped sharply over 30 days from peak deaths by a mean of 74%, in close time conjunction with *MOT* start date (Fig. 1B). In 14 states of Peru having locally administered IVM distributions, the mean reduction in excess deaths over 30 days from peak deaths was 53%, while in Lima, which had minimal IVM distributions during the first wave of the pandemic due to restrictive government policies there, the corresponding 30-day decrease in excess deaths was 25%.

Reductions in excess deaths by state (absolute values) correlated with the extent of IVM distribution (maximal-*MOT* states, moderate-local distributions, and minimal-Lima) with Kendall $\tau_b = 0.524$, $p < 0.002$, as shown in Fig. 1C. Nationwide, excess deaths decreased 14-fold over four months through 1st December 2020. After a restrictive IVM treatment policy was

enacted under a new Peruvian president who took office on 17th November, however, deaths increased 13-fold over the two months following 1st December through 1st February 2021 (Fig. 1A). Potential confounding factors, including lockdowns and herd immunity, were ruled out using Google community mobility data, seropositivity rates, population densities and geographic distributions of SARS-CoV-2 genetic variations and by restricting all analysis except that for Fig. 1A to ages $\geq$ 60. Excess deaths were used in all analyses rather than COVID-19 case fatalities as gross underreporting of pandemic deaths by case fatalities was known to the Peruvian Ministry of Health since July 2020 [43]. This disparity has been consistently manifested in the national health database figures for COVID-19 case fatalities vs. all natural-cause deaths since that date [42].

IVM-based combination treatments and other research in progress

Combination treatments using IVM and adjuncts have shown indications of efficacy against COVID-19 in RCTs conducted to date [24,44]. Results using IVM, doxycycline and zinc to treat serious and critical cases having spO2 $\leq$ 90 prior to treatment, with spO2 changes tracked 24 hours after treatment, will be reported by TJB with Sabine Hazan, MD. Pronounced improvements of serious COVID-19 symptoms within 1–2 days after IVM administration have been observed in several patients treated by the lead author (ADS), and studies to objectively track such short-term clinical benefits of IVM for COVID-19 are underway. Information on other combination treatments using IVM with agents such as fluvoxamine, for which clinical studies also indicate significant benefits [45], is provided by the USA-based FLCCC alliance (https://covid19criticalcare.com).

The curative potential of combination therapy was demonstrated in a medical breakthrough of three decades prior for another disease, peptic ulcers, for which the discovery of its underlying bacterial cause, *Helicobacter pylori,* was honoured with the Nobel Prize for Medicine in 2005. In 1990, Dr Thomas J. Borody published the original clinical trial of a combination treatment for *H. pylori*, achieving a 96% cure rate for a triple therapy consisting of three repurposed drugs, bismuth subcitrate and two antibiotics [46]. Between 1990 and 2015, an estimated 18,665 deaths were prevented by the timely application of this triple therapy for peptic ulcer disease in Australia [47]. After the expiration of the patents for two palliative drugs for this condition, Tagamet and Zantac [48], which had each earned billions of dollars, triple therapy became the standard of care for peptic ulcers in the rest of the world by the late 1990s.

Conclusion

We believe that the evidence to date supports the worldwide extension of IVM treatments for COVID-19, complementary to immunizations. The indicated biological mechanism of IVM, competitive binding with SARS-CoV-2 spike protein, is likely non-epitope specific, as reviewed [8], possibly yielding full efficacy against emerging viral mutant strains. IVM has been safely used in 3.7 billion doses since 1987, well tolerated even at much greater than standard doses [34,35] and used without serious AEs in the three high-dose COVID-19 treatment studies noted above [34,36,37]. In the current international emergency of COVID-19, with mutant viral strains, vaccination refusals and potentially waning immunities over months presenting new challenges, IVM can be an effective component of the mix of therapeutics deployed against this pandemic.

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Ethical approval and consent to participate

This is a review and ethical approval was not required.

Transparency declaration

TJB is a principal in Topelia Therapeutics (Ventura, California), which seeks to commercialize cost-effective treatments for COVID-19, including IVM. All other authors report no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.nmni.2021.100924.

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New COVID-19 Treatments Add-On Payment (NCTAP)

CMS issued an Interim Final Rule with Comment Period that established the New COVID-19 Treatments Add-on Payment (NCTAP) under the Medicare Inpatient Prospective Payment System (IPPS). The NCTAP, designed to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments, is effective from November 2, 2020, until the end of the COVID-19 public health emergency (PHE).

Through the NCTAP, the Medicare Program will provide an enhanced payment for eligible inpatient cases that use certain new products with current FDA approval or emergency use authorization (EUA) to treat COVID-19, including the following:

- On August 23, 2020, the FDA issued (reissued on November 30, 2020, and revised on March 9, 2021) an EUA for the use of COVID-19 convalescent plasma for treating COVID-19 in hospitalized patients
- On October 22, 2020, the FDA approved remdesivir (Veklury) for the treatment of COVID-19 for adults and certain pediatric patients requiring hospitalization
- On November 19, 2020, the FDA issued an EUA for the use of baricitinib (Olumiant), in combination with remdesivir (Veklury), for the treatment of suspected or laboratory confirmed COVID-19 in certain hospitalized patients

For eligible cases, the NCTAP is equal to the lesser of these:

- 65% of the operating outlier threshold for the claim
- 65% of the amount by which the costs of the case exceed the standard Diagnosis-Related Group (DRG) payment (including the adjustment to the relative weight under Section 3710 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

Coding for NCTAP

following:

- ICD-10-CM diagnosis code U07.1 (COVID-19)
- ICD-10-PCS codes for remdesivir (Veklury), COVID-19 convalescent plasma, or baricitinib (Olumiant) in combination with remdesivir, as described below

Codes for Remdesivir or COVID-19 Convalescent Plasma for Hospital Discharges on or after November 2, 2020

ICD-10-PCS Code	Description
XW033E5	Introduction of remdesivir anti-infective into peripheral vein, percutaneous approach, new technology group 5
XW043E5	Introduction of remdesivir anti-infective into central vein, percutaneous approach, new technology group 5
XW13325	Transfusion of convalescent plasma (nonautologous) into peripheral vein, percutaneous approach, new technology group 5
XW14325	Transfusion of convalescent plasma (nonautologous) into central vein, percutaneous approach, new technology group 5

Codes for Baricitinib for Hospital Discharges between November 19, 2020 and December 31, 2020*

ICD-10-PCS Code	Description
XW0DXF5	Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5

PCS Code	Description
3E0G7GC	Introduction of other therapeutic substance into upper G.I. via natural or artificial opening
3E0H7GC	Introduction of other therapeutic substance into lower G.I. via natural or artificial opening

*In accordance with the EUA, providers should administer baricitinib with remdesivir. Claims should also include the code for remdesivir (XW033E5 or XW043E5).

Codes for Baricitinib for Hospital Discharges on or after January 01, 2021 through the End of the COVID-19 PHE*

ICD-10-PCS Code	Description
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6

*In accordance with the EUA, providers should administer baricitinib with remdesivir. Claims should also include the code for remdesivir (XW033E5 or XW043E5).

Hospitals should report the ICD-10-PCS code(s) for all products administered during the stay, even if the hospital got the product for free. Hospitals shouldn't report charges for products they got for free.

Note:
A hospital shouldn't seek additional payment on the claim for drugs or biologicals to treat patients with known or suspected COVID-19 that the government purchased or provided for free. See the CMS

For more information on COVID-19 diagnosis and procedure codes, visit the "Latest News" section of the MS-DRG Classifications and Software webpage.

You can also review our COVID-19 FAQs (PDF), which include information on NCTAP and our implementation of Section 3710 of the CARES Act.

Related Links

- CMS COVID-19 webpage
- CMS COVID-19 FAQs
- CMS COVID-19 toolkits
- CDC COVID-19 website

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The Vaccine Adverse Event Reporting System (VAERS) Results

Vaccine Type	Events Reported	Percent (of 24,671)
ADENOVIRUS TYPE 4 &7 VACCINE, LIVE ORAL (ADEN_4_7)	1	0.00%
ANTHRAX VACCINE (ANTH)	10	0.04%
CHOLERA VACCINE (CHOL)	3	0.01%
COVID19 VACCINE (COVID19)	26,311	106.65%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (DTAP)	26	0.11%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE (DTAPIPV)	7	0.03%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	12	0.05%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	19	0.08%
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE (DTP)	1	0.00%
DIPHTHERIA AND TETANUS TOXOIDS, PEDIATRIC (DT)	2	0.01%
EBOLA ZAIRE VACCINE (EBZR)	2	0.01%
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	24	0.10%
HEPATITIS A (HEPA)	17	0.07%
HEPATITIS B VACCINE (HEP)	33	0.13%
HUMAN PAPILLOMAVIRUS (TYPES 6, 11, 16, 18) RECOMBINANT VACCINE (HPV4)	12	0.05%
HUMAN PAPILLOMAVIRUS (TYPES 6, 11,16, 18, 31, 33, 45, 52, 58) RECOMBINANT VACCINE (HPV9)	52	0.21%
INFLUENZA (H1N1) MONOVALENT (INJECTED) (FLU(H1N1))	1	0.00%
INFLUENZA VIRUS VACCINE, NO BRAND NAME (FLUX(SEASONAL))	27	0.11%
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	86	0.35%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, ADJUVANT (INJECTED) (FLUA4(SEASONAL))	6	0.02%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, CELL-CULTURE-DERIVED (INJECTED) (FLUC4(SEASONAL))	6	0.02%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, RECOMBINANT (INJECTED) (FLUR4(SEASONAL))	10	0.04%
INFLUENZA VIRUS VACCINE, TRIVALENT (INJECTED) (FLU3(SEASONAL))	11	0.04%
INFLUENZA VIRUS VACCINE, TRIVALENT, ADJUVANT (INJECTED) (FLUA3(SEASONAL))	10	0.04%
INFLUENZA VIRUS VACCINE, TRIVALENT, CELL-CULTURE-DERIVED (INJECTED) (FLUC3(SEASONAL))	1	0.00%
INFLUENZA(H1N1) MONOVALENT, UNKNOWN MANUFACTURER (FLUX(H1N1))	1	0.00%
JAPANESE ENCEPHALITIS VIRUS VACCINE, INACTIVATED, ADSORBED (JEV1)	1	0.00%
MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE (MMR)	35	0.14%
MEASLES, MUMPS, RUBELLA, AND VARICELLA VACCINE (PROQUAD) (MMRV)	9	0.04%
MENINGOCOCCAL B VACCINE (MENB)	11	0.04%
MENINGOCOCCAL POLYSACCHARIDE VACCINE (MEN)	3	0.01%
MENINGOCOCCAL VACCINE (MENACTRA) (MNQ)	11	0.04%
PNEUMOCOCCAL VACCINE, POLYVALENT (PPV)	26	0.11%
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	46	0.19%
POLIOVIRUS VACCINE INACTIVATED (IPV)	6	0.02%
POLIOVIRUS VACCINE TRIVALENT, LIVE, ORAL (OPV)	1	0.00%
RABIES VIRUS VACCINE (RAB)	15	0.06%
ROTAVIRUS (NO BRAND NAME) (RVX)	2	0.01%
ROTAVIRUS VACCINE, LIVE, ORAL (RV1)	6	0.02%
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	19	0.08%
TETANUS AND DIPHTHERIA TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (BOOSTRIX/ADACEL) (TDAP)	36	0.15%
TETANUS TOXOID (TTOX)	1	0.00%
TYPHOID VACCINE (TYP)	2	0.01%
VARIVAX-VARICELLA VIRUS LIVE (VARCEL)	16	0.06%
YELLOW FEVER VACCINE (YF)	2	0.01%
ZOSTER VACCINE (VARZOS)	360	1.46%
UNKNOWN VACCINES (UNK)	438	1.78%
Total	**27,737**	**112.43%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information. (/wonder/help/vaers.html#Suppress)

Data contains VAERS reports processed as of 10/08/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

Values of Event Category field vary in their availability over time due to changes in the reporting form. The "Emergency Room/Office Visit" value was avaliable only for events reported using the VAERS-1 form, active 07/01/1990 to 06/29/2017. The "Congenital Anomaly/Birth Defect", "Emergency Room", and "Office Visit" values are available only for events reported using the VAERS 2.0 form, active 06/30/2017 to present. These changes must be considered when evaluating count of events for these categories.

About COVID19 vaccines:

- For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/).
- One report may state that the patient received more than one brand of COVID-19 vaccine on the same visit. This is a reporting error, but explains why the total number of reports may not equal the total number of COVID-19 vaccine doses.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Oct 20, 2021 7:38:25 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 10/08/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Oct 20, 2021 7:38:25 PM

Query Criteria:

Date Report Received:	2021
Event Category:	Death; Life Threatening; Permanent Disability
State / Territory:	The United States/Territories/Unknown
Group By:	Vaccine Type
Show Totals:	True
Show Zero Values:	False

From: Anelia Mollova
To: DPBH StateBOH
Subject: Strongly oppose mandatory Covid vaccinations for children
Date: Thursday, December 2, 2021 3:54:22 PM

I strongly oppose mandatory vaccinations for children, and especially the new Corona virus vaccine. Children's risk of severe illness or death from SARS-COV2 is extremely low. The injury rate of just one of the many adverse events from covid vaccination being tracked by VAERS; myocarditis, is significantly higher than the risk of the disease it is meant to protect children from.

In addition, each current covid vaccine available in the U.S. is under Emergency Use Authorization. The only FDA approved covid vaccine is not currently available to consumers in the U.S.

Parents must be the only people responsible to make health and medical choices for their children, and no medical treatment should be coerced or mandated upon children.

Let's not forget that because these vaccines do not prevent infection or transmission of SARS-COV2 but are advertised as a way to reduce symptoms and severity of illness in the injected person, covid vaccination cannot be represented as a "public health" measure which has any effect on anyone but the person injected.

Anelia Mollova, concerned parent

From:	Dr. Turner
To:	DPBH StateBOH
Cc:	Gmail 2
Subject:	meeting comments 12/3/21
Date:	Thursday, December 2, 2021 3:47:40 PM

Dear Dr. Jon Pennell, DVM; Dr. Jeffrey Murawsky, MD; Dr. Trudy Larson, MD; Dr. Monica Ponce', DDS; Judith Bittner and Charles Smith:
I am contacting you today about any current or future consideration by the Nevada Board of Health to require that children receive COVID vaccines as a requirement for school enrollment and attendance in the state of Nevada.

I strongly oppose any such measure.

My reasons are:

1. Children have the lowest risk of severe disease or death and we must question whether the risk of mRNA vaccine injury outweighs the risk of mild covid disease in 99.99% of children. If we can not answer that question through rigorous controlled studies or post EUA monitoring, it is unethical to simply assume a positive risk reward outcome in this population.

2. Children may have an advantage in getting mild disease as a younger child vs. getting a more severe disease a child ages. Per the CDC, current mRNA vaccines do not prevent spread or infection, but they often prolong the time to infection as vaccine antibodies wane. Saying vaccines prevent serious disease or death is moot in a population that statically already has no risk of serious disease or death.

3. Children who have been in school have likely been covid-exposed and already have robust and durable immunity.

4. There is ample evidence that covid infection and recovery provides robust and durable immunity. Per the CDC, there is no evidence recovered people get repeat covid infections or spread covid. The narrative discounting post-infection

immunity to support mRNA vaccination is spurious and false. It is well known that recovery from an infection will always provide more reliable immunity than a vaccine for the same disease. Here are 81 studies that say exactly that.

5. Children with robust and durable immunity post-covid infection are already the foundation of community immunity. Vaccination is not necessary to provide this. Vaccination risk of myocarditis, clots, and neuropathy is well know at this point. Vaccines do not provide long lasting immunity or prevent transmission, but vaccine side effects can be severe and life -altering.

6. This age groups is doing just fine without vaccination. There are not deaths or severe disease among children 5-17. They are not apparently spreading covid to adults, teachers, parents, or grandparents. The vaccine is available for any parent that elects to have their child take it. There is no need for an emergency mandate of covid vaccine for this age group.

7. This is the line in the sand for many. Nevada families will leave public school in favor of homeschooling. Public schools can't exist without students. Mandates and school closures have already done more harm than good.

8. These vaccines are currently under EUA, not FDA approved for uptake in children ages 5-15. Per federal law, any product licensed under an EUA requires that citizens and therefore in the case of minor children, their parents/legal guardians, have the option to accept or refuse the product. It is unethical and illegal to mandate these products.

In closing, to sum this up one can look at covid disease like a freight train or a tricycle. There is no argument that for certain populations over 65, getting covid can be like being hit by a freight train. And the risk of vaccines adverse effects for someone at or near their life span with high risk may be something they will accept. However, for kids, covid disease is more like being hit by a tricycle. But the small risk of vaccine adverse event, largely unknown at this point, can be like being hit -- quite unnecessarily -- by a freight train.

Best Regards,
Caroline Turner

Nevada Board of Health Meeting December 3 2021

Agenda Item 3 – Health reports

Southern Nevada Health District Report

> **All of this reporting is skewed**. **The testing process is completely discriminatory**. Therefore, there is no way that these numbers are fully accurate as the **unvaccinated are being forced to test much more than the vaccinated.** This would naturally lead to higher positive cases overall for the unvaccinated. Even though both can equally contract and transmit based on the attached study and admission by the CDC director. This complete discrimination is still going on. Discriminatory treatment of the unvaccinated in hospitals is also happening.

The real time database for this reporting that you are basing the livelihoods of Nevada residents on should be disclosed and made public so we can do our own research. The report screen they have published has zero ability to be verified. (Transparency is federal regulated over you)

The APA requires that "administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished ad hoc determinations." Morton v. Ruiz, 415 U.S. 199, 232 (1974). The Freedom of Information Act amended the APA to advance this goal, and generally requires that agencies publish in the Federal Register their substantive rules of general applicability, statements of general policy, and interpretations of law that are generally applicable. 5 U.S.C. 552(a)(1)(D). Unless a party has actual and timely notice of the terms of a rule or policy, the Freedom of Information Act generally provides that a party may not be adversely affected by a rule or policy required to be published in the Federal Register that is not so published. 5 U.S.C. 552(a)(1)(flush language). This rule of agency procedure ensures that HHS actions comport with these requirements. II.

For a personal example, in my husband's fire station, two fully COVID vaccinated individuals got very sick and tested positive for COVID, the department doctor required the individuals who were contact traced and unvaccinated to quarantine for 10 days and take a negative COVID test before going back to work even though they had previously survived a COVID infection and had ZERO SYMPTOMS and also never did get sick from this contact. However, **the sick individuals got cleared to go back once they said they felt better and were not required to quarantine a certain time nor were they required to test to return to work.**

This is a major flaw in the entire pandemic handling and the numbers over 2 years.

I have also attached a study that was released by Harvard University on natural immunity being 13x better than the vaccine, so this would prove that you need to **start visiting some hospitals and see what is really going on.**

PS: I find it amusing that the entire STATE is COVID, COVID, COVID vaccines, masks, etc. Yet when you develop your CHIP team **the 4 priorities that are the focus of the community COVID did not make the list**. Hypocrisy at its best! Obviously the public wants to move on from this.

See attached: Law requiring transparency, testing inaccuracy letter from FDA plus recall of tests, natural immunity study, virus shedding higher in vaccinated

[signature]

Elizabeth Hammack - Henderson Nevada

Innova Medical Group Recalls Unauthorized SARS-CoV-2 Antigen Rapid Qualitative Test with Risk of False Test Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- **Innova SARS-CoV-2 Antigen Rapid Qualitative Test** (also distributed under the names Innova COVID-19 Self-Test Kit (3T Configuration), Innova SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration), and Innova SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration))
- **Lot codes:**
    - **25T (25 tests per box) -** U2101750, U2101751, X2006004, X2008001, X2008010, X2009002, X2009004, X2009013, X2009016, X2010004, X2010010, X2011005, X2011006, X2011007, X2011008, X2011009, X2011012, X2011013, X2011015, X2011016, X2011017, X2011025, X2011051, X2011052, X2012001, X2012002, X2012004, X2012005, X2012008, X2101002, X2101004, X2101014, X2101031, X2101038
    - **3T (3 tests per box) -** U2102003, X2012310
    - **7T (7 tests per box) -** U2101748, U2102001, U2102002, X2012711, X2103792
- **Manufacturing Dates:** September 1, 2020 to March 3, 2021
- **Distribution Dates:** November 2, 2020 to March 22, 2021
- **Devices Recalled in the U.S.:** At least 77,339
- **Date Initiated by Firm:** March 24, 2021

Device Description

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test claimed to determine if a person has an active COVID-19 infection. The test used a nasal swab sample and test strip to detect specific proteins, called antigens, from the SARS-CoV-2 virus. If the nasal sample had SARS-CoV-2 antigens, a colored test line should have appeared on the test strip, indicating that the person

should not have appeared on the test strip. The test has not been authorized, cleared, or approved by FDA for commercial distribution in the United States.

Reason for Recall

Innova Medical Group is recalling its SARS-CoV-2 Antigen Rapid Qualitative Test. Labeling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during the clinical studies of the tests. The performance characteristics of the test have not been adequately established, presenting a risk of false results.

- **False-negative results** may lead to delayed diagnosis or inappropriate treatment of SARS-CoV-2, which may cause patient harm including serious illness and death. False-negative results can also lead to further spread of the SARS-CoV-2 virus, including when presumed negative patients are grouped into cohorts in health care, long-term care, and other facilities based on false test results.
- **False-positive results** could lead to a delay in the correct diagnosis and the initiation of an appropriate treatment for the actual cause of patient illness, which could be another life-threatening disease that is not SARS-CoV-2. False-positive results could also lead to further spread of the SARS-CoV-2 virus when presumed positive patients are grouped into cohorts based on false test results.

Who May Be Affected

- People who were tested using these devices
- Health care providers who may have access to and use these tests or whose patients have used these tests
- Organizers of large testing programs, such as on college campuses, who may be using and distributing these tests for diagnostic use

What to Do

On April 23, 2021, Innova Medical Group sent all affected device users an Urgent Medical Device Recall letter. The letter provided the following information:

- Do not use these tests to screen for or diagnose COVID-19.
- Identify and remove all affected tests from inventory.
- Either destroy the tests by placing them in the trash or return the tests using the FedEx return label that was included with the letter Innova sent to its customers.

destroyed or returned tests.

The FDA also recommends:

- **Test users and caregivers:** Talk to your health care provider if you think you were tested with the Innova SARS-CoV-2 Antigen Rapid Qualitative Test and you have concerns about your test results.
- **Health care providers:** If the test was given less than two weeks ago, consider retesting your patients using a different SARS-CoV-2 diagnostic test if you suspect an inaccurate result. If testing was performed more than two weeks ago and there is no reason to suspect current SARS-CoV-2 infection, it is not necessary to retest.
- **Testing program organizers:** Notify participants in your testing program to discontinue diagnostic use of these tests and to use an FDA-authorized test to continue testing. For listings of FDA-authorized tests, see:
    - FDA-Authorized Molecular Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - FDA-Authorized Antigen Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
- Report any problems you experience with the Innova SARS-CoV-2 Antigen Rapid Test to the FDA, including suspected false results.

For more information, please see the FDA's June 2021 safety communication, Stop Using Innova SARS-CoV-2 Antigen Rapid Qualitative Test (/medical-devices/safety-communications/stop-using-innova-medical-group-sars-cov-2-antigen-rapid-qualitative-test-fda-safety-communication).

Contact Information

Customers with questions about this recall should contact Linda Weinreb at Linda.Weinreb@innovamedgroup.com (mailto:Linda.Weinreb@innovamedgroup.com) or call 747-494-0852.

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event

Risk of False Results with the Curative SARS-Cov-2 Test for COVID-19: FDA Safety Communication

The Curative, Inc., Curative SARS-Cov-2 Assay (originally authorized as the Korvalabs, Inc. Curative-Korva SARS-Cov-2 Assay) Emergency Use Authorization was revoked at the company's request effective July 15, 2021, because the company is now using different EUA-authorized tests for the testing offered at its laboratories. The test that is the subject of this safety communication is no longer being offered and is no longer authorized for emergency use by the FDA.

Date Issued: January 4, 2021

The U.S. Food and Drug Administration (FDA) is alerting patients and health care providers of the risk of false results, particularly false negative results, with the Curative SARS-Cov-2 test. Risks to a patient of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

To reduce the risk of false negative results, it is important to perform the test in accordance with its authorization and as described in the authorized labeling, e.g., the Fact Sheet for Healthcare Providers (/media/137087/download). When the test is not performed in accordance with its authorization or as described in the authorized labeling, there is a greater risk that the results of the test may not be accurate.

Important Recommendations for Health Care Providers, Patients, and Caregivers

- Be aware of the important information regarding the use of the Curative SARS-Cov-2 test, which is described in the test's authorized labeling, including the following:
  - Collection of nasal swabs and oral fluid specimens is limited to symptomatic individuals within 14 days of COVID-19 symptom onset.
  - Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.
  - A negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

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suspect an inaccurate result was given *recently* by the Curative SARS-Cov-2 test. If testing was performed more than two weeks ago, and there is no reason to suspect current SARS-Cov-2 infection, it is not necessary to retest.

- **Patients and caregivers:** Talk to your health care provider if you think you were tested with the Curative SARS-Cov-2 test (the test name is displayed on this test's authorized Fact Sheets and, generally, the Fact Sheets must be provided with test result reports) and you have concerns about your test results.
- Report any problems you experience with the Curative SARS-Cov-2 test to the FDA, including suspected inaccurate results.

Device Description

The Curative SARS-Cov-2 Assay is a real-time RT-PCR test used to detect SARS-Cov-2, the virus that causes COVID-19. This test is authorized for prescription-only use. The test is performed by collecting a throat swab, nasopharyngeal swab, nasal swab, or oral fluid specimen from an individual suspected of COVID-19 by their health care provider. Under the Emergency Use Authorization, the specimen is then to be processed at the KorvaLabs, Inc., laboratory, and results are returned to the patient.

Consistent with the test's authorized labeling (/media/137087/download), collection of nasal swabs and oral fluid specimens is limited to individuals who have shown symptoms of COVID-19 within 14 days of onset of the symptoms. Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.

Consistent with the EUA summary (/media/137089/download), negative results for SARS-Cov-2 RNA from oral fluid specimens should be confirmed by testing of another specimen type authorized for use with this test if clinically indicated.

FDA Actions

The FDA regularly monitors the post-authorization use of tests, including reports of problems with test performance or results, and is providing this information to help educate patients, caregivers, and health care providers and reduce the risk of false results.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with a Medical Device

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including problems with test performance or results," through MedWatch (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program), the FDA Safety Information and Adverse Event Reporting program.

Generally, as specified in a test's EUA, device manufacturers and authorized laboratories must comply with applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.

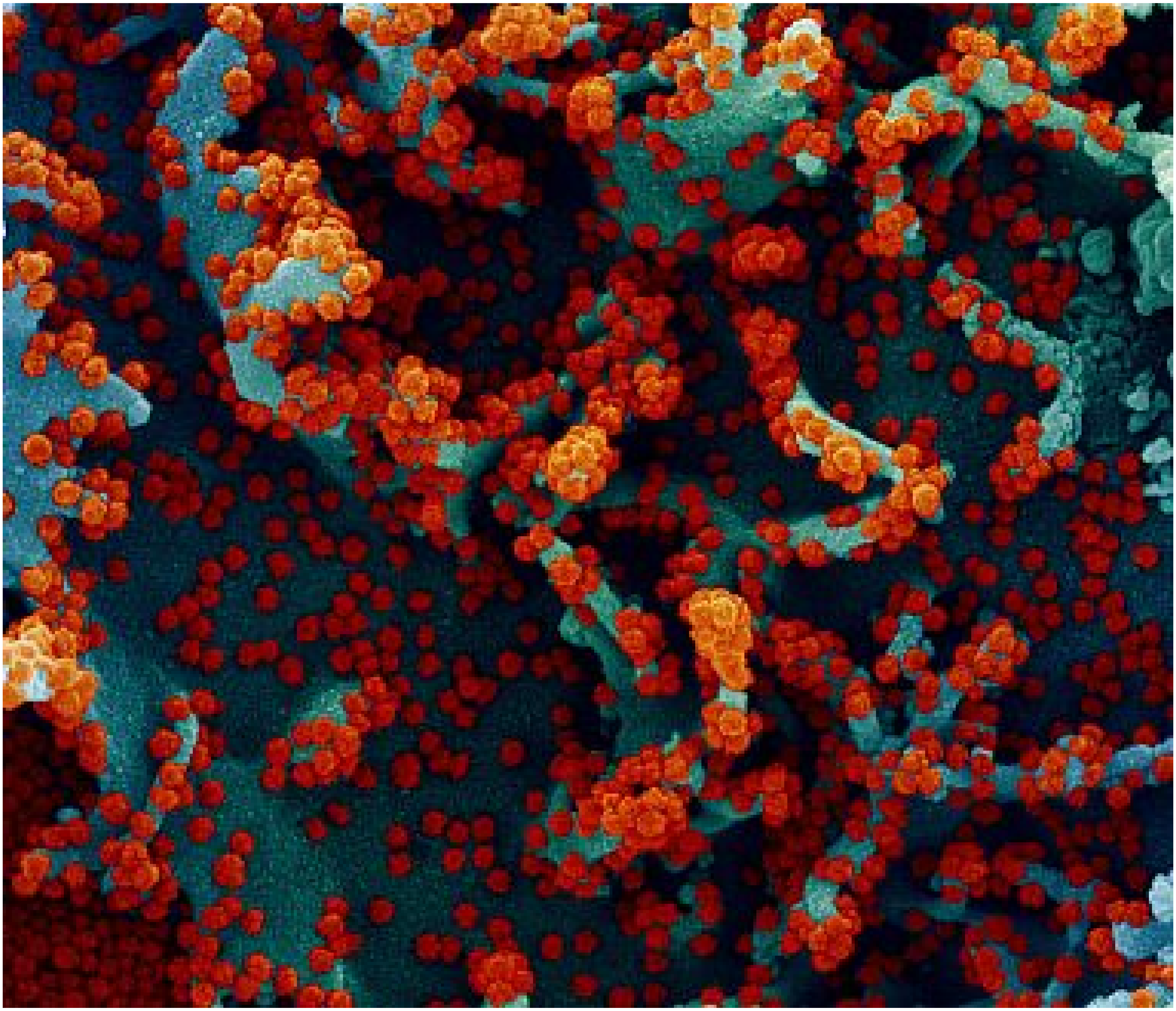
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January 26, 2021

Lasting immunity found after recovery from COVID-19

At a Glance

- The immune systems of more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection.
- The results provide hope that people receiving SARS-CoV-2 vaccines will develop similar lasting immune memories after vaccination.



Colorized scanning electron micrograph of a cell, isolated from a patient sample, that is heavily infected with SARS-CoV-2 virus particles (red). *NIAID Integrated Research Facility, Fort Detrick, Maryland*

After people recover from infection with a virus, the immune system retains a memory of it. Immune cells and proteins that circulate in the body can recognize and kill the pathogen if it's encountered again, protecting against disease and reducing illness severity.

This long-term immune protection involves several components. Antibodies—proteins that circulate in the blood—recognize foreign substances like viruses and neutralize them. Different types of T cells help recognize and kill pathogens. B cells make new antibodies when the body needs them.

All of these immune-system components have been found in people who recover from SARS-CoV-2, the virus that causes COVID-19. But the details of this immune response and how long it lasts after infection have been unclear. Scattered reports of reinfection with SARS-CoV-2 have raised concerns that the immune response to the virus might not be durable.

To better understand immune memory of SARS-CoV-2, researchers led by Drs. Daniela Weiskopf, Alessandro Sette, and Shane Crotty from the La Jolla Institute for Immunology analyzed immune cells and antibodies from almost 200 people who had been exposed to SARS-CoV-2

and recovered.

Time since infection ranged from six days after symptom onset to eight months later. More than 40 participants had been recovered for more than six months before the study began. About 50 people provided blood samples at more than one time after infection.

The research was funded in part by NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI). Results were published on January 6, 2021, in *Science*.

The researchers found durable immune responses in the majority of people studied. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset. As seen in previous studies, the number of antibodies ranged widely between individuals. But, promisingly, their levels remained fairly stable over time, declining only modestly at 6 to 8 months after infection.

Virus-specific B cells increased over time. People had more memory B cells six months after symptom onset than at one month afterwards. Although the number of these cells appeared to reach a plateau after a few months, levels didn't decline over the period studied.

Levels of T cells for the virus also remained high after infection. Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus. These cells help coordinate the immune response. About half the participants had CD8+ T cells, which kill cells that are infected by the virus.

As with antibodies, the numbers of different immune cell types varied substantially between individuals. Neither gender nor differences in disease severity could account for this variability. However, 95% of the people had at least 3 out of 5 immune-system components that could recognize SARS-CoV-2 up to 8 months after infection.

"Several months ago, our studies showed that natural infection induced a strong response, and this study now shows that the responses last," Weiskopf says. "We are hopeful that a similar pattern of responses lasting over time will also emerge for the vaccine-induced responses."

—by Sharon Reynolds

Related Links

- Experimental Coronavirus Vaccine Highly Effective (https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective)
- Antibodies and T Cells Protect Against SARS-CoV-2 (https://www.nih.gov/news-events/nih-research-matters/antibodies-t-cells-protect-against-sars-cov-2)
- Immune Cells for Common Cold May Recognize SARS-CoV-2 (https://www.nih.gov/news-events/nih-research-matters/immune-cells-common-cold-may-recognize-sars-cov-2)
- Potent Neutralizing Antibodies Target New Regions of Coronavirus Spike (https://www.nih.gov/news-events/nih-research-matters/potent-neutralizing-antibodies-target-new-regions-coronavirus-spike)
- Potent Antibodies Found in People Recovered from COVID-19 (https://www.nih.gov/news-events/nih-research-matters/potent-antibodies-found-people-recovered-covid-19)
- Novel Coronavirus Structure Reveals Targets for Vaccines and Treatments (https://www.nih.gov/news-events/nih-research-matters/novel-coronavirus-structure-reveals-targets-vaccines-treatments)
- Coronavirus (COVID-19) (https://covid19.nih.gov/)
- Coronavirus Prevention Network (https://www.coronaviruspreventionnetwork.org/)

- Coronavirus (COVID-19) (https://www.coronavirus.gov/)

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Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections

Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon

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Abstract

Background Reports of waning vaccine-induced immunity against COVID-19 have begun to surface. With that, the comparable long-term protection conferred by previous infection with SARS-CoV-2 remains unclear.

Methods We conducted a retrospective observational study comparing three groups: (1)SARS-CoV-2-naïve individuals who received a two-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine, (2)previously infected individuals who have not been vaccinated, and (3)previously infected *and* single dose vaccinated individuals. Three multivariate logistic regression models were applied. In all models we evaluated four outcomes: SARS-CoV-2 infection, symptomatic disease, COVID-19-related hospitalization and death. The follow-up period of June 1 to August 14, 2021, when the Delta variant was dominant in Israel.

breakthrough infection with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant (*P*<0.001) for symptomatic disease as well. When allowing the infection to occur at any time before vaccination (from March 2020 to February 2021), evidence of waning natural immunity was demonstrated, though SARS-CoV-2 naïve vaccinees had a 5.96-fold (95% CI, 4.85 to 7.33) increased risk for breakthrough infection and a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic disease. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalizations compared to those that were previously infected.

Conclusions This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. Individuals who were both previously infected with SARS-CoV-2 and given a single dose of the vaccine gained additional protection against the Delta variant.

Competing Interest Statement

The authors have declared no competing interest.

Funding Statement

There was no external funding for the project.

Author Declarations

I confirm all relevant ethical guidelines have been followed, and any necessary IRB and/or ethics committee approvals have been obtained.

Yes

The details of the IRB/oversight body that provided approval or exemption for the research described are given below:

This study was approved by the MHS (Maccabi Healthcare Services) Institutional Review Board (IRB). Due to the retrospective design of the study, informed consent was waived by the IRB, and all identifying details of the participants were removed before computational analysis.

All necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived.

I understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).

Yes

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

Yes

Footnotes

- The authors declare they have no conflict of interest.
- **Funding:** There was no external funding for the project.

Paper in collection COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

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Preprint discussion sites covering this article:

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PUBPEER PubPeer, 30 Aug 2021

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Shedding of Infectious SARS-CoV-2 Despite Vaccination

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Abstract

The SARS-CoV-2 Delta variant might cause high viral loads, is highly transmissible, and contains mutations that confer partial immune escape [1,2]. Outbreak investigations suggest that vaccinated persons can spread Delta [3,4]. We compared RT-PCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin 29 June through 31 July 2021 and tested with a qualitative assay by a single contract laboratory. Specimens came from residents of 36 counties, most in southern and southeastern Wisconsin, and 81% of cases were not associated with an outbreak. During this time, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and state immunization records (**Supplemental Figure 1**).

Main text

We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%; **Figure 1A**) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people (**Figure 1B**).

Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing (**Figure 1C**). Ct values <25 were detected in 7 of 24 unvaccinated (29%; CI: 13-51%) and 9 of 11 fully vaccinated asymptomatic individuals (82%; CI: 48-97%), and 158 of 232 unvaccinated (68%, CI: 62-74%) and 156 of 225 fully vaccinated (69%; CI: 63-75%) symptomatic individuals. Time from symptom onset to testing did not vary by vaccination status (p=0.40; **Supplemental Figure 2**). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although few asymptomatic individuals were sampled, these results indicate that even asymptomatic, fully vaccinated people might shed infectious virus.

Combined with other studies [2–5], these data indicate that vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-

2 is frequently found even in vaccinated persons when specimen Ct values are low. The inclusion of viruses from Pango lineages B.1.617.2, AY.2, and AY.3, and multiple counties without a linking outbreak, indicate that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent with transmissibility in fully vaccinated individuals across a range of settings. Vaccinated and unvaccinated persons should get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19. Continued adherence to non-pharmaceutical interventions during periods of high community transmission to mitigate spread of COVID-19 remain important for both vaccinated and unvaccinated individuals.

Figure

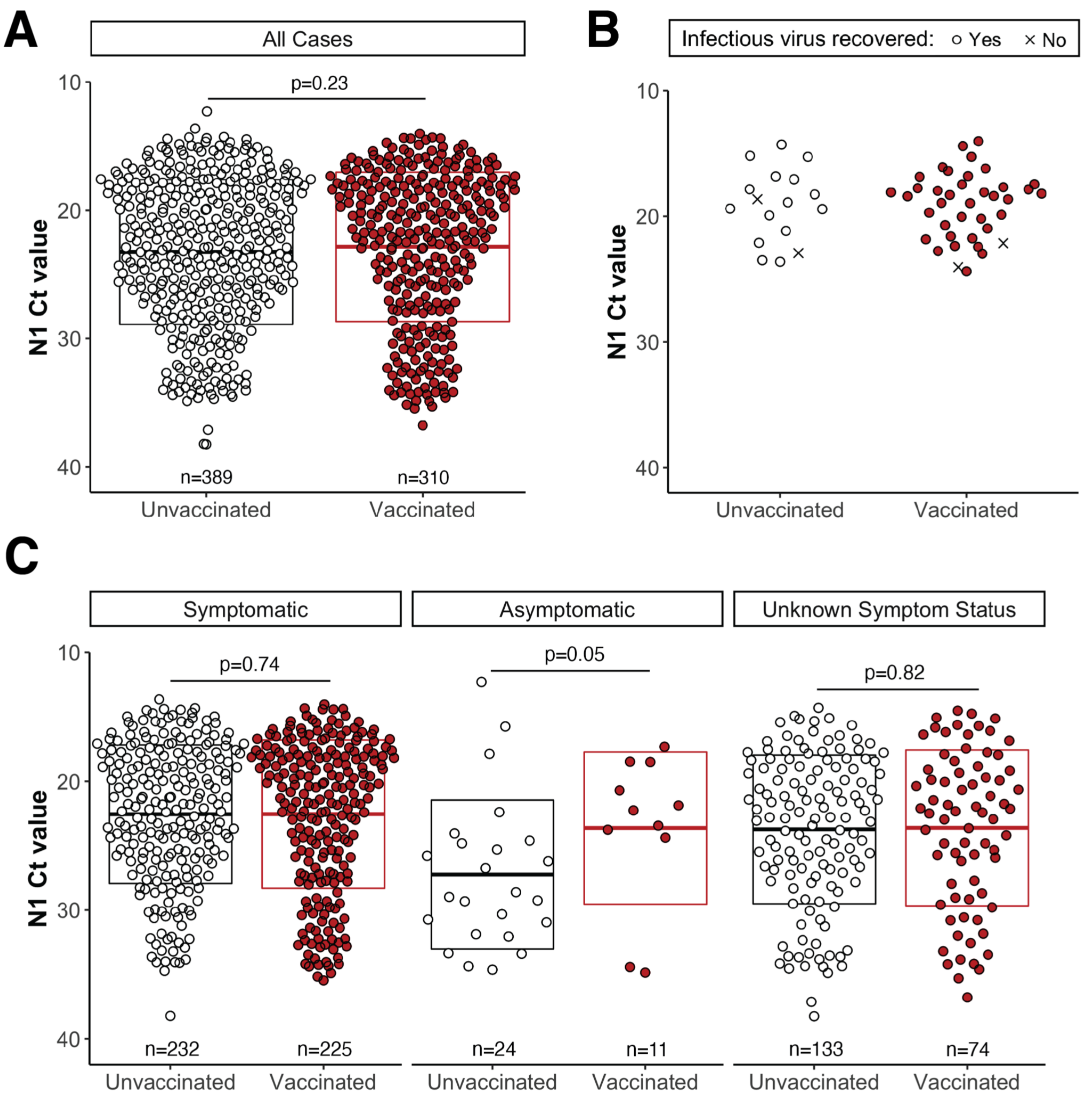


Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values and shed infectious virus. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. RT-PCR was performed by Exact Sciences Corporation, responsible for over 10% of all PCR tests in Wisconsin during this period, using a qualitative diagnostic assay targeting the SARS-CoV-2 N gene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized for emergency use by FDA (https://www.fda.gov/media/138328/download). **B.** Infectiousness was determined for a subset of N1 Ct-matched specimens with Ct <25 by inoculation onto Vero E6 TMPRSS2 cells and determining presence of cytopathic effects (CPE) after 5 days in culture. Specimens were selected by N1 Ct-matching between fully vaccinated and not fully vaccinated persons, then specimens from persons with unknown vaccination status were excluded from the analysis. Circles indicate presence of CPE; 'X' indicates no CPE detected. **C.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic or asymptomatic, or those whose symptom status was not determined, at the time of testing. In **A** and **C**,

boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

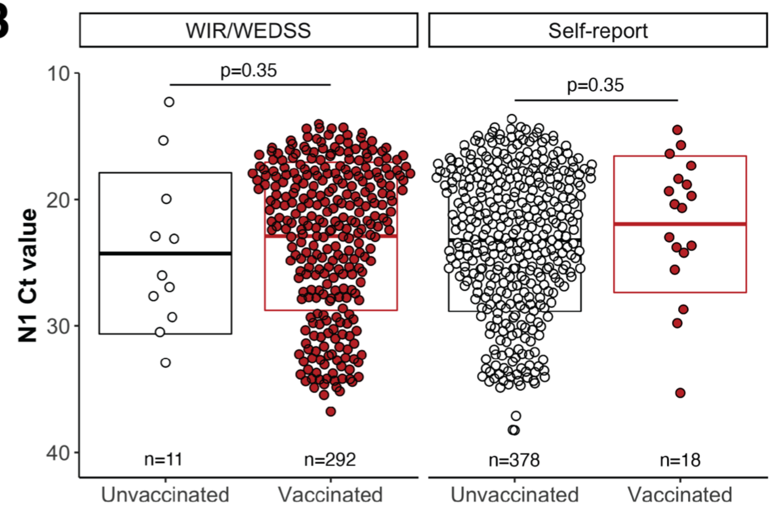
Supplemental materials

Supplemental figure 1

A

		Vaccinated per self-report: Yes	Vaccinated per self-report: No
Vaccinated per WIR or WEDSS	Yes	124	33
	No	0	8

B



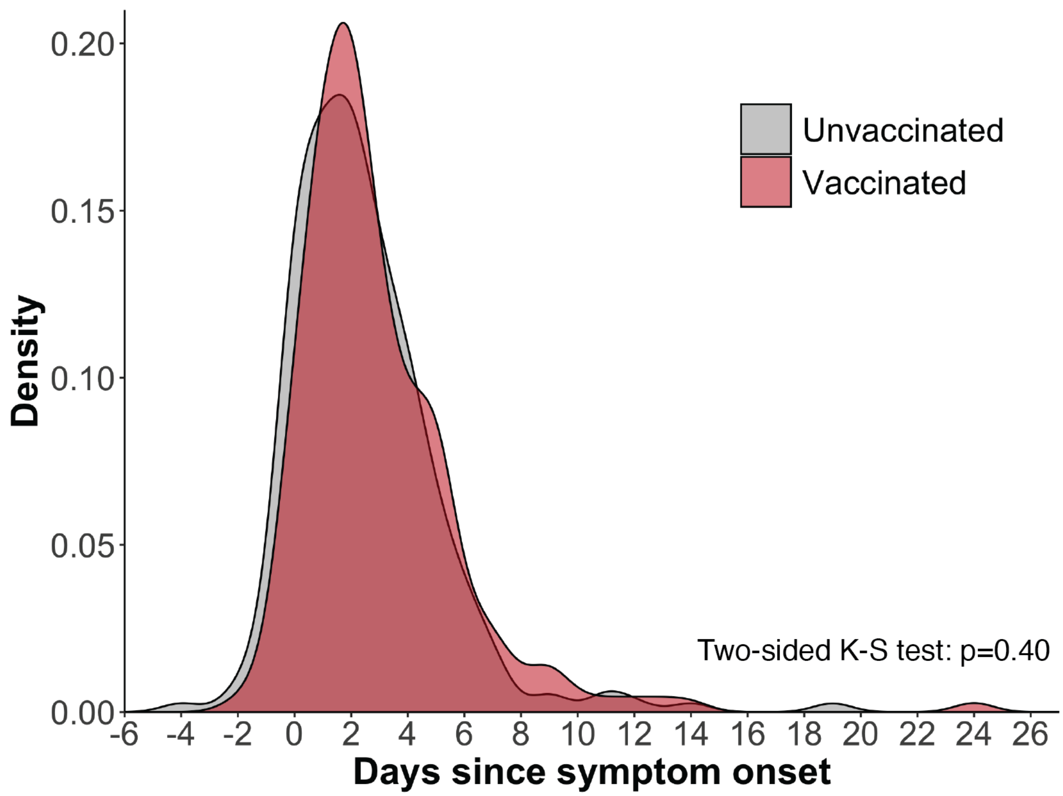
Supplemental figure 1. Concordance between self-reported vaccination status and the Wisconsin Immunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For all individuals, vaccination status was determined using WIR/WEDSS electronic registries when data were available. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS data indicated receipt of a first SARS-CoV-2 vaccine dose after the test date.

Individuals were considered fully vaccinated based on WIR/WEDSS data if the registries indicated receipt of a final vaccine dose at least 14 days prior to testing. For individuals whose vaccination status could not be verified in WIR/WEDSS, self-reported data collected at the time of testing were used. Individuals were considered unvaccinated based on self-report only if there was an explicit declaration of unvaccinated status in the self-reported data. Individuals were considered fully vaccinated based on self-report if they fulfilled all of the following criteria: (1) indicated that they had received a COVID vaccine prior to testing; (2) indicated that they did not require another vaccine dose; and (3) reported a date of last vaccine dose that was at least 14 days prior to testing.

Specimens lacking data on vaccination status were excluded from the study. Specimens from partially vaccinated individuals (incomplete vaccine series, or <14 days post-final dose) were also excluded. Fully vaccinated status was determined by WIR/WEDSS for 292 specimens and by self-reported data for 18. Unvaccinated status was determined by WIR/WEDSS for 11 and by self-reported data by 378. **A.** Of the 699 specimens with vaccination status available from at least one source, 165 specimens had data available from both sources. For self-reporting, under-reporting of full vaccination status (33/157) was more common than over-reporting (0/124). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals whose vaccination status was determined by WIR/WEDDS or by self-reported data. Boxplots represent mean N1 Ct values +/- one standard

deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental figure 2



Supplemental figure 2. Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=263 unvaccinated cases and n=232 vaccinated cases.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(l)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

The opinions expressed by authors contributing to this journal do not necessarily reflect the opinions of the Centers for Disease Control and Prevention or the institutions with which the authors are affiliated.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, culture status, and days from symptom onset to testing for each specimen.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 1

HHS-OS-2021-0001

RIN: 0991-AC18

Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services is issuing regulations promoting transparency and fairness in civil enforcement actions. These regulations will help to ensure that regulated parties receive fair notice of laws and regulations they are subject to, and have an opportunity to contest an agency determination prior to the agency taking an action that has a legal consequence.

DATES: Effective January 12, 2021.

FOR FURTHER INFORMATION CONTACT:

Brenna Jenny, Department of Health and Human Services, 200 Independence, Avenue, S.W., Room 713F, Washington, D.C. 20201. Email: Good.Guidance@hhs.gov. Telephone: (202) 690-7741.

I. Statutory and Regulatory Background

The primary legal authority supporting this rulemaking is 5 U.S.C. 301. That provision provides that the "head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." This statute authorizes an "agency to regulate its own affairs," and issue rules, such as this one, that are "rules of agency organization[,] procedure or practice." *Chrysler Corp. v.*

Brown, 441 U.S. 281, 309-10 (1979). Similarly, 42 U.S.C. 1302 provides that the Secretary "shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged" under Chapter 7 of the Social Security Act. Chapter 7 contains, among other things, statutory provisions governing Medicare, Medicaid, and the Health Insurance Portability and Accountability Act (HIPAA).

The Administrative Procedure Act ("APA"), 5 U.S.C. 551 *et seq.,* specifies the process by which such regulations are promulgated. Department heads generally must prescribe regulations through notice-and-comment rulemaking, but there is an exception for "rules of agency organization, procedure, or practice." The requirements for notice and comment prior to finalization also do not apply to regulations that involve "a matter relating to agency management or personnel." 5 U.S.C. 553(a)(2).

Because this final rule only specifies procedures that agency personnel must follow or that will govern civil enforcement actions, it is exempt from the requirement for notice and comment prior to finalization. In determining whether notice-and-comment rulemaking is required, the "critical feature is that [the rule] covers agency actions that do not themselves alter the rights or interests of the parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency." *Nat'l Sec. Counselors v. CIA*, 931 F. Supp. 2d 77, 106-07 (D.D.C. 2013) (quoting *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980)). This rule is exempt from notice and comment because it does not "put[] a stamp of approval or disapproval on a given type of behavior." *Am. Hosp. Assoc. v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987). What had been a regulatory violation prior to finalization of this rule still is; the Department of Health and Human Services ("HHS" or "the Department") is only modifying the procedures governing civil enforcement actions and the Department's civil enforcement action practices. To be sure, these procedural modifications, like most rules of agency procedure or personnel, might have some impact on the public. But agency rules that impose "derivative,"

"incidental," or "mechanical" burdens upon regulated individuals are considered procedural, rather than substantive, and are therefore exempt from the notice-and-comment requirement. *Id.* at 1051. Moreover, to the extent this rule has effects on the public, it only provides additional protections to the public, rather than depriving the public of any rights or interests it previously had.

The APA requires that "administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished *ad hoc* determinations." *Morton v. Ruiz,* 415 U.S. 199, 232 (1974). The Freedom of Information Act amended the APA to advance this goal, and generally requires that agencies publish in the Federal Register their substantive rules of general applicability, statements of general policy, and interpretations of law that are generally applicable. 5 U.S.C. 552(a)(1)(D). Unless a party has actual and timely notice of the terms of a rule or policy, the Freedom of Information Act generally provides that a party may not be adversely affected by a rule or policy required to be published in the Federal Register that is not so published. 5 U.S.C. 552(a)(1)(flush language). This rule of agency procedure ensures that HHS actions comport with these requirements.

II. Summary of Transparency and Fairness Regulations

To provide regulated parties with greater transparency and fairness in administrative actions, and consistent with the requirements of Executive Order 13892 of October 9, 2019, "Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication," 84 FR 55239 (Oct. 15, 2019), HHS is setting forth policies that promote transparency and fairness in civil enforcement actions that will apply to all divisions of HHS. The requirements in this rule amend 45 CFR part 1.

This rule is one component of the Department's broader regulatory reform initiative. The rule is designed to ensure accountability, fairness of how the Department uses guidance, proper

use of guidance documents, and opportunities for third parties to be heard, and to safeguard the important principles underlying the United States administrative law system.

A. Scope (45 CFR 1.1)

The requirements established pursuant to this rule in §§ 1.2(b) and 1.6 through 1.9 apply to civil enforcement actions by any component of the Department. Sections 1.3 through 1.5 (as well as the definitions in § 1.2 that were added through the Good Guidance Practices final rule at 85 FR 78770 (Dec. 7, 2020), and that we will recodify in this rule at § 1.2(a)) will continue to apply to all guidance documents until FDA amends its good guidance practices regulation to be consistent with the HHS Good Guidance Practices rule, at which point §§ 1.2(a) and 1.3 through 1.5 shall apply to all divisions of HHS except FDA.

Nothing in this rule shall apply:

- To any action that pertains to foreign or military affairs, or to a national security or homeland security function of the United States (other than procurement actions and actions involving the import or export of nondefense articles and services);
- To any action related to a criminal investigation or prosecution, including undercover operations, or any civil enforcement action or related investigation by the Department of Justice, including any action related to a civil investigative demand under 18 U.S.C. 1968;
- To any action related to detention, seizure, or destruction of counterfeit goods, pirated goods, or other goods that infringe intellectual property rights;
- To any investigation of misconduct by an agency employee or any disciplinary, corrective, or employment action taken against an agency employee; or
- In any other circumstance or proceeding to which application of this order, or any part of this order, would, in the judgment of the Secretary of HHS, undermine the national security.

B. Definitions (45 CFR 1.2)

The definitions section at 45 CFR 1.2 is amended to include the following definitions at paragraph (b).

Civil Enforcement Action

HHS defines "civil enforcement action" to mean an action with legal consequence taken by the Department based on an alleged violation of the law. Such actions include administrative enforcement proceedings and enforcement adjudication (which is the administrative process undertaken by any component of the Department to resolve the legal rights and obligations of specific parties with regard to a particular enforcement issue pending before it) but do not include actions taken in the normal course of the Department's regulatory communications or decision-making, for example, decisions on product applications (such as approvals or denials/withdrawals of approval), claims authorizations, responses to citizen petitions, food or color additive petitions, or public health notifications.

Legal Consequence

HHS defines "legal consequence" as the result of an action that directly or indirectly affects substantive legal rights or obligations including by subjecting a regulated party to potential liability in an enforcement action. The meaning of this term is informed by the Supreme Court's discussion in *U.S. Army Corps of Engineers v. Hawkes Co.*, 136 S. Ct. 1807, 1813–16 (2016), and includes, for example, agency letters or orders establishing or increasing the probability of liability for regulated parties in a subsequent enforcement action, *Ipsen Biopharmaceuticals, Inc. v. Azar*, 943 F.3d 953, 956 (D.C. Cir. 2019); *Rhea Lana, Inc.* v. *Dep't of Labor,* 824 F.3d 1023, 1030 (D.C. Cir. 2016). It does not include a warning letter or other communication, such as one describing inspectional observations, that pursuant to agency policy is intended to provide notice to a regulated party and elicit voluntary compliance. Such warning letters and inspectional observations have no immediate regulatory implications for the entity, are an interim step in the agency's compliance communications with an entity, and are not final

agency action that has legal consequences for a party. *See Orton Motor, Inc. v. HHS*, 884 F.3d 1205, 1215 (D.C. Cir. 2018); *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012); *see also Hi-Tech Pharm., Inc. v. Hahn*, Civ. No. 19-1268(RBW), 2020 WL 3498588, *5 (D.D.C. June 29, 2020); *Lystn, LLC v. FDA*, No. 19-cv-1943-PAB-KLM, 2020 WL 248962, *5 (D. Colo. Jan. 16, 2020); *Cody Labs., Inc. v. Sebelius*, No. 10-CV-00147-ABJ, 2010 WL 3119279, *11 (D. Wyo. July 26, 2010), *aff'd*, 446 F. App'x 964, 969 (10th Cir. 2011); *Gomperts v. Azar*, No. 1:19-cv-00345-DCN, 2020 WL 3963864, *4–5 (D. Idaho July 13, 2020).

Unfair Surprise

HHS defines "unfair surprise" to mean a lack of reasonable certainty or fair warning, from the perspective of a reasonably prudent member of regulated industry, of what a legal standard administered by an agency requires, or the initiation of litigation by HHS following "a very lengthy period of conspicuous inaction," in other words deliberate inaction, suggesting the agency previously had a different interpretation. *Christopher* v. *SmithKline Beecham Corp.,* 567 U.S. 142, 156 (2012). However, an agency does not create unfair surprise when it proceeds with a new interpretation that it established in notice-and-comment rulemaking. *See Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 158 (1991) (identifying "adequacy of notice to regulated parties" as one factor relevant to the reasonableness of the agency's interpretation).

The definitions currently at 45 CFR 1.2 will be moved into a new paragraph (a). All definitions at paragraph (a) apply to all components of HHS until FDA amends its good guidance practices regulation, at which point the definitions at 45 CFR 1.2(a) shall apply to all divisions of HHS except FDA. The definitions at § 1.2(b) will apply to all components of the Department, including FDA.

C. Proper Department Reliance on Guidance Documents (45 CFR 1.6)

This rule reiterates the application of certain existing legal principles to HHS's use of guidance documents: When the Department takes a civil enforcement action or otherwise makes

a determination based on an alleged violation of law that has legal consequence for a person or state, it must allege or establish the violation of law by applying statutes or regulations. HHS may not use guidance documents to impose binding requirements or prohibitions on persons outside of the executive branch except as authorized by law or expressly incorporated into a contract. Noncompliance with a standard or practice that is not in a statute or regulation and announced solely in a guidance document may not be treated as itself a violation of applicable statutes or regulations, unless expressly authorized by statute.

This rule also explains the appropriate circumstances when the Department may use a guidance document in civil enforcement actions. The Department may use a guidance document to explain the legal applicability of a statute or regulation with regard to prohibition of conduct, but when it does so, HHS may only use the guidance document to articulate the Department's understanding of how a statute or regulation applies to particular circumstances. Except when referring to a guidance document for historical facts, the Department may reference a guidance document in a civil enforcement action only if it has notified the public of such document to convey that understanding in advance. The Department must notify the public in advance of a guidance document through publication in the Department's guidance repository (as described in § 1.4 and available at hhs.gov/guidance).

D. Fairness and Notice in Civil Enforcement Actions and Administrative Inspections (45 CFR 1.7)

This rule would require the Department to only apply standards or practices that have been publicly stated in a manner that would not cause unfair surprise when HHS takes a civil enforcement action or otherwise makes a determination based on an alleged violation of law that has legal consequence for a person or state, unless a statutory exception applies. *See, e.g.*, 42 U.S.C. 1395hh(e). For purposes of this regulation, the Department would consider standards or practices to be publicly stated if available in paper publications or on the internet.

HHS avoids unfair surprise not only when it imposes penalties but also whenever it adjudges past conduct to have violated the law. For example, the Department generally cannot retroactively impose liability on a party for conduct that violates a new agency interpretation. *But see* 42 U.S.C. 1395hh(e). The Department also may not alter its interpretation during an adjudicative proceeding if doing so would impose new liability on parties who have acted in good faith on the prior interpretation. *SmithKline Beecham*, 567 U.S. at 156 & n.15.

Section 7 of Executive Order 13892 requires that each agency that conducts civil administrative inspections must publish a rule of agency procedure governing such inspections, if such a rule does not already exist. The Department is adding a requirement at 45 CFR 1.7 that HHS shall only conduct civil administrative inspections according to published rules of agency procedure. While the Administrative Procedure Act exempts these subsequently issued rules of agency procedure themselves from notice-and-comment rulemaking, *see* 5 U.S.C. 553(b)(3)(A), each agency must make the rules governing its civil administrative inspections, including audits, publicly available and readily accessible, such as by posting them on a website.

E. <u>Fairness and Notice in Jurisdictional Determinations (45 CFR 1.8)</u>

The requirement for fairness and notice also extends to jurisdictional determinations. If the Department relies on a decision previously issued by an agency within the Department in an agency adjudication (*i.e.*, proceedings before and decided by the agency), administrative order, or agency document to assert a new or expanded claim of jurisdiction (*e.g.*, a claim to regulate a new subject matter or a new basis for liability, or a relinquishment of a claim of jurisdiction), the Department must give fair notice by publishing the initial decision in the *Federal Register* or the Department's guidance repository. *See* 45 CFR 1.4. The Department should not rely on the new claim of jurisdiction to take a civil enforcement action regarding conduct that occurred before such publication. A claim of jurisdiction is not "new or expanded" simply because it involves a

new or novel set of facts so long as it is based on an established principle of general applicability.

If the Department intends to rely on a document arising out of litigation (other than a publicly published opinion of an adjudicator) such as a brief, a consent decree, or a settlement agreement, to establish jurisdiction in future civil enforcement actions involving persons who were not parties to the litigation, the Department must also publish that document in the *Federal Register* or on the Department's guidance repository. Alongside publication of the document, the Department must also provide an explanation of the document's jurisdictional implications. Publication of a document discussed in this paragraph may either be in full or by citation, if the document is publicly available.

HHS is also proposing that if the Department seeks judicial deference to its interpretation of a document arising out of litigation (other than a publicly published opinion of an adjudicator) in order to establish a new or expanded claim of jurisdiction, HHS must, before seeking judicial deference, publish the document or a notice of availability in the *Federal Register* or on the Department's guidance repository, along with an explanation of the document's jurisdictional implications.

F. Opportunity to Contest Agency Determinations (45 CFR 1.9)

Providing regulated parties with the opportunity to be heard, including through informal oral or written communications, prior to the Department taking any civil enforcement action that has legal consequence is critical to ensuring that the Department operates with transparency and fairness. This rule will require that, before any component of the Department takes any civil enforcement action with respect to a particular entity that has legal consequence for that entity—including by issuing to such a person a notice of noncompliance or other similar notice that has immediate regulatory consequence or the immediate effect of subjecting the person to potential liability—the Department must afford that person an opportunity to be heard, either orally or in writing, as deemed appropriate at the Department's election. The rule will require HHS to

provide the person with its proposed legal and factual determinations and then give the person a reasonable amount of time to respond to those determinations. The specific timeframe shall be in the discretion of the agency but must be long enough to provide a meaningful opportunity to be heard. Certain circumstances may warrant a time period of 30 days, while other circumstances may warrant a shorter period, such as 15 days or fewer, particularly where existing agency procedures already offer a shorter period in which to respond. Unless the Department withdraws the action, the Department must then respond in writing to the regulated party and articulate the final basis for the Department's action. This written response may be issued contemporaneous to the Department taking the action with legal consequence. We anticipate that generally, existing HHS procedures will already satisfy these standards, and where they do, those existing procedures will continue in effect unchanged. This rulemaking is not intended to preempt existing rules of agency procedure that are already consistent with this rule. Furthermore, where the Department takes an action based on a predicate finding that was reached following notice, an opportunity to be heard, and a written response, for example, where the Department revokes Medicare enrollment based on a prior exclusion or felony conviction, these procedural requirements are considered to have already been satisfied.

These procedures regarding fair notice and an opportunity to respond would not apply where the agency, in its discretion, determines there is a serious threat to health, safety, or similar emergency, or where a statute specifically authorizes proceedings that are inconsistent with this section, including proceedings without a prior opportunity to be heard. Where such a threat arises and a statute does not specifically authorize proceedings without a prior opportunity to be heard, HHS would still provide an affected entity with an opportunity to be heard and a written response as soon as practicable. In this context, a serious threat means that, as reasonably determined by the Department, there is a non-negligible likelihood of the threat materializing.

We anticipate that the exception from § 1.9 for actions taken in the context of threats to health, safety, or similar emergencies will apply broadly to public health agencies acting in

furtherance of their missions. Actions will be considered to fall into this exception regardless of whether there is a showing of actual, imminent risk or harm, either to persons or animals. The agency has sole discretion to determine when an action falls into this exception. An agency may invoke this exception regardless of whether agency action is taken reactively (*e.g.*, to address an unsafe item currently on the market) or proactively (*e.g.*, to enforce regulations needed to protect public health prior to actual exposure by the public to unsafe items). Actions that fall into this exception include, for example, enforcing age restrictions or other controls around access to certain regulated products, enforcing manufacturer recordkeeping or reporting requirements, enforcing premarket requirements where there is an absence of or insufficient data concerning the product, protecting beneficiary data privacy or a federal healthcare program beneficiary from harm, and taking action to remove unapproved, misbranded, or adulterated human or animal products from the market.

Because of this exception, the procedures in § 1.9 generally will not impact, for example, the administrative detention process for foods, drugs, devices, and tobacco products (21 U.S.C. 334(g), (h)), the detention, refusal, and where authorized, destruction of imported products regulated by FDA (21 U.S.C. 381), disqualification (21 CFR parts 56, 58, 312, 511, 812), administrative detention, recall requests, import alerts, or other public notifications about food, drug, device, or tobacco products, or other actions related to investigating adulterated or misbranded products.

These procedures would also not apply to settlement negotiations between agencies and regulated parties, to notices of a prospective legal action, where a statute specifically precludes review of agency action, or to litigation before courts. Examples of situations where statutes specifically authorize differently structured proceedings include, but are not limited to, the hospital cost report appeals process (42 U.S.C. 1395oo), the individual benefit claims appeals process (42 U.S.C. 1395ff), and the process for the review of disallowances of Medicaid expenditures by the Secretary (42 U.S.C. 1316(e)). In such circumstances, the process and

substantive standards governing review of claims arising under a relevant statute or regulation remain governed by those more specific procedures. The procedures would also not apply to any action related to a criminal investigation or prosecution, including undercover operations that may be used in a criminal investigation or prosecution, or any civil enforcement action either related to an investigation by the Department of Justice, or referred to the Department of Justice.

III. Rulemaking Analyses and Notices

A. Executive Orders 12866 and 13563

Executive Order 12866, "Regulatory Planning and Review," and Executive Order 13563, "Improving Regulation and Regulatory Review," direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select regulatory approaches that maximize net benefits. The Department does not believe that this rulemaking is a significant regulatory action under these Executive Orders. This rule describes an update to the Department's current processes to ensure that it operates with transparency and fairness. The requirements in 45 CFR 1.6 through 1.9 relating to the proper use of guidance documents and fairness and notice in enforcement actions generally already exist in law. The requirements set forth in Section 6 of Executive Order 13892 and codified at 45 CFR 1.6 may exceed the requirements imposed by the Due Process clause of the Constitution and may impose a burden by delaying the time until HHS can take actions with legal consequence. However, this process will also offer important procedural safeguards and potentially reduce economic costs borne by regulated entities, which will have an opportunity to respond in writing before the Department takes an action that has (potentially costly) legal consequence.

The Department anticipates that the public, and, in particular, regulated parties, would benefit from greater efficiencies and more transparency in how the Department regulates, including facilitating smoother operations within HHS by clearly defining how guidance can be used.

B. Executive Order 13771

This final rule is neither a regulatory nor a deregulatory action under Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs," 82 FR 9339 (Feb. 3, 2017), because this rule is estimated to impose no more than de minimis costs on regulated entities.

C. Regulatory Flexibility Act

The Department has examined the economic implications of this rule as required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq*. The RFA requires an agency to describe the impact of a rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency expects that the rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). The Department considers a proposed or final rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. The Department anticipates that this rule will allow small entities to operate more efficiently, by increasing the transparency of government regulation. As a result, the Department has determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of a substantial number of small entities.

D. Executive Order 13132 (Federalism)

Executive Order 13132, "Federalism," establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has Federalism implications. The Department has determined that this final rule will not impose such costs or have any federalism implications.

E. Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, 44 U.S.C. 3501–3521; 5 CFR part 1320, the Department has reviewed this rule and has determined that it imposes no new collections of information.

List of Subjects in 45 CFR Part 1

Guidance, Government employess.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR Part I as set forth below:

PART 1—TRANSPARENCY AND FAIRNESS IN CIVIL ADMINISTRATIVE ENFORCEMENT AND ADJUDICATION

1. The authority citation for part 1 continues to read as follows:

Authority: 42 U.S.C. 1302, 5 U.S.C. 301, 551 *et seq*.

2. Section 1.1 is revised to read as follows:

§ 1.1 Scope.

Sections 1.2(a) and 1.3 through 1.5 of this part shall apply to guidance documents issued by all components of the Department, until the Secretary amends the Food and Drug Administration's good guidance regulations at 21 CFR 10.115 to bring them into conformance with the requirements of this part, at which point, such amended regulations shall apply to the Food and Drug Administration, and §§ 1.2(a) and 1.3 through 1.5 shall apply to all divisions of the Department except the Food and Drug Administration. Sections 1.2(b) and 1.6 through 1.9 of this part shall apply to all components of the Department.

3. Section 1.2 is amended by designating the existing text as paragraph (a) followed by the alphabetical ordered definitions, revising newly designated paragraph (a) introductory text, and adding paragraph (b).

The revision and addition read as follows:

§ 1.2 Definitions.

(a) The following definitions apply to all components of the Department until the Secretary amends the Food and Drug Administration's good guidance regulations at 21 CFR 10.115 to bring them into conformance with the requirements of §§ 1.3 through 1.5 of this part:

*   *   *   *   *

(b) The following definitions apply to all components of the Department:

Civil enforcement action means an action with legal consequence taken by the Department based on an alleged violation of the law. Such actions include administrative enforcement proceedings and enforcement adjudication (which is the administrative process undertaken by any component of the Department to resolve the legal rights and obligations of specific parties with regard to a particular enforcement issue pending before it) but do not include actions taken in the normal course of the Department's regulatory communications or decision-making, for example, decisions on product applications (such as approvals, denials, or withdrawals of approval), claims authorizations, citizen petitions, food or color additive petitions, or public health notifications.

Legal consequence means the result of an action that directly or indirectly affects substantive legal rights or obligations, including by subjecting a regulated party to potential liability in an enforcement action. This includes agency letters or orders establishing greater liability for regulated parties in a subsequent enforcement action, but excludes communications that have no immediate regulatory implications for a person or entity, such as letters (*e.g.*, warning letters) or inspectional observations that serve as an interim step in the agency's compliance communications with a person or entity or that are intended to encourage voluntary compliance.

Unfair surprise means a lack of reasonable certainty or fair warning, from the perspective of a reasonably prudent member of regulated industry, of what a legal standard administered by an agency requires.

4. Section 1.6 is added to read as follows:

§ 1.6 Proper Department reliance on guidance documents.

(a) *Overview*. A civil enforcement action must have an appropriate legal basis. When the Department takes a civil enforcement action or makes a determination based on an alleged

violation of law that has legal consequence for a person or state, it must allege or establish the violation of law by applying statutes or regulations.

(b) *Limitations on the use of guidance documents.* (1) The Department may not use guidance documents to impose binding requirements or prohibitions on persons outside the executive branch except as expressly authorized by law or as expressly incorporated into a contract.

(2) The Department may not treat noncompliance with a standard or practice announced solely in a guidance document as itself a violation of applicable statutes or regulations except as expressly authorized by law.

(3) If the Department uses a guidance document to explain the legal applicability of a statute or regulation, that document can do no more, with respect to prohibition of conduct, than articulate the Department's understanding of how a statute or regulation applies to particular circumstances.

(4) The Department may cite to a guidance document in a civil enforcement action only if it has notified the public of such document in advance through publication, in the Department's guidance repository, as described in § 1.4.

5. Section 1.7 is added to read as follows:

§ 1.7 Fairness and notice in civil enforcement actions and administrative inspections.

(a) When the Department takes a civil enforcement action, the Department may only apply standards or practices that have been publicly stated in a manner that would not cause unfair surprise.

(b) The Department must avoid unfair surprise when it imposes penalties and whenever it adjudges past conduct to have violated the law.

(c) The Department shall only conduct civil administrative inspections according to published rules of agency procedure.

6. Section 1.8 is added to read as follows:

§ 1.8 Fairness and notice in jurisdictional determinations.

(a) If the Department relies on a decision in an agency adjudication, administrative order, or agency document to assert a new or expanded claim of jurisdiction (*e.g.*, a claim to regulate a new subject matter or a new basis for liability, or a relinquishment of a claim of jurisdiction), the Department must give fair notice by publishing the initial decision before the conduct over which jurisdiction is sought occurs. It must publish the initial decision in full or by citation, if publicly available, in the *Federal Register* or the Department's guidance repository described in § 1.4. A claim of jurisdiction is not "new or expanded" simply because it involves a new or novel set of facts so long as it is based on an established principle of general applicability.

(b) If the Department intends to rely on a document arising out of litigation (other than a publicly published opinion of an adjudicator), such as a brief, a consent decree, or a settlement agreement, to establish jurisdiction in future civil enforcement actions involving persons who were not parties to the litigation, the Department must—

(1) Publish that document, either in full or by citation if publicly available, in the *Federal Register* or on the Department's guidance repository described in § 1.4, and

(2) Publish an explanation of the document's jurisdictional implications.

(c) Before seeking judicial deference to the Department's interpretation of a document arising out of litigation (other than a publicly published opinion of an adjudicator) in order to establish a new or expanded claim of jurisdiction in a different case, the Department must—

(1) Publish the document or a notice of availability in the *Federal Register* or on the Department's guidance repository described in § 1.4, and

(2) Publish an explanation of the document's jurisdictional implications.

7. Section 1.9 is added to read as follows:

§ 1.9 Opportunity to contest agency determination.

(a) *Departmental overview*. Except as provided in paragraph (c) of this section, prior to the Department taking any civil enforcement action with respect to a particular entity that has

legal consequence for that entity, including by issuing to such a person a notice of noncompliance, or other similar notice that has immediate regulatory consequence, but excluding communications that have no immediate regulatory implications for the entity, such as those that serve as an interim step in the agency's compliance communications with the entity or that are intended to encourage voluntary compliance, the Department shall provide—

(1) Written notice to the affected entity of the initial legal and factual determinations underpinning the initial adverse determination;

(2) An opportunity for the affected entity to respond in writing and, if determined appropriate by the Department, orally; and

(3) A written response from the Department to the affected entity after receiving a timely request from the affected entity under paragraph (a)(2) of this section.

(b) *Timing and content of written responses*. (1) The Department will select a meaningful amount of time in which the affected entity must submit a written response to the Department. This writing must be submitted within the time period specified by the Department, unless the Department concludes an extension is warranted, and state the reasons for the entity's disagreement with the Department's proposed action for purposes of requiring a response in accordance with paragraph (a)(3) of this section.

(2) The Department's written response must respond to the affected entity and articulate the basis for its final decision. This written response may be issued contemporaneous to the Department taking the action with legal consequence.

(c) *Exceptions*. The procedures in paragraphs (a) and (b) of this section do not apply where the Department, in its discretion, determines there is a serious threat to health, safety, or similar emergency, or where a statute specifically authorizes proceeding without a prior opportunity to be heard. In such event, HHS would still provide an affected entity with an opportunity to be heard and a written response as soon as practicable. The procedures in paragraphs (a) and (b) do not apply to settlement negotiations between agencies and regulated

parties, to notices of a prospective legal action, to litigation before courts, or any action related to a criminal investigation or prosecution, including undercover operations that may be used in a criminal investigation or prosecution, or any civil enforcement action either related to an investigation by the Department of Justice, or referred to the Department of Justice.

Dated: January 7, 2021.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.

[FR Doc. 2021-00592 Filed: 1/12/2021 4:15 pm; Publication Date: 1/14/2021]

Thursday, December 2, 2021

Notice of Maladministration

To: Nevada Board of Health (DPBH)
4150 Technology Way
Carson City, Nevada 89706
Email: StateBOH@health.nv.gov

Cc:______________________
____
____

NOTICE OF MALADMINISTRATION
TO NEVADA BOARD OF HEALTH MEETING 12/03/2021 9:00 AM:

Notice to Agent is Notice to Principal and Notice to Principal is Notice to Agent

I, printedName, one of the People as seen in the Declaration of Rights of the Nevada state Constitution, am giving you this notice so that you and your agents may provide due care as I am an aggrieved taxpayer; I'll be watching via https://dpbh.nv.gov/Boards/BOH/Meetings/2021/NVBOH2021/

The liberty interest of a parent in the care, custody and management of the parent's child is a fundamental right. (See NRS 126.036 and Nevada Constitution Article 1 Section 1 stated below)

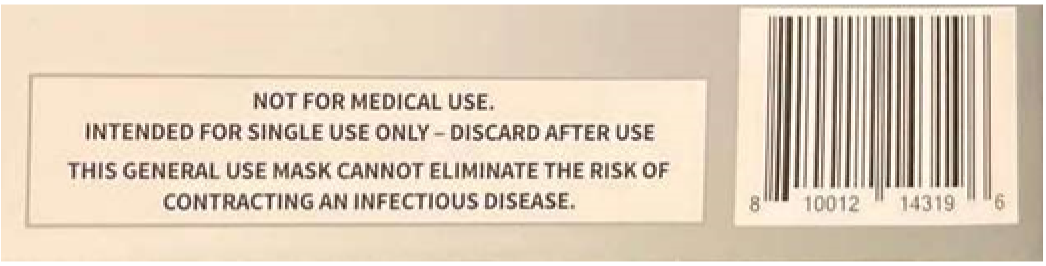
PLEASE TAKE NOTICE OF NEVADA CONSTITUTION DECLARATION OF RIGHTS ARTICLE 1:

Sec. 1: "Inalienable rights. All men are by Nature free and equal and have certain inalienable rights among which are those of enjoying and defending life and liberty; Acquiring, Possessing and Protecting property and pursuing and obtaining safety and happiness[.]"

Sec: 10: "The people shall have the right freely to assemble together to consult for the common good, to instruct their representatives and to petition the Legislature for redress of Grievances." (Emphasis added)

Sec: 17: "Neither Slavery nor involuntary servitude unless for the punishment of crimes shall ever be tolerated in this State." FORCING CHILDREN TO WEAR MASKS IS INVOLUNTARY SERVITUDE! Requiring our children to wear MASKS that are not even intended for a medical use and cannot eliminate the risk of an infectious disease, is EVIDENCE OF CHILD ABUSE AND MALADMINISTRATION!





Sec. 8A. Rights of victims. 1. Each person who is the victim of a crime is entitled to the following rights:
(a) To be treated with fairness and respect for his or her privacy and dignity, and to be free from intimidation, harassment and abuse, throughout the criminal or juvenile justice process. OUR CHILDREN ARE VICTIMS!
(b) To be reasonably protected from the defendant and persons acting on behalf of the defendant.
2. A victim has standing to assert the rights enumerated in this section in any court with jurisdiction over the case. . . . and 4. A person may maintain an action to compel a public officer or employee to carry out any duty required by this section or any statute enacted by the Legislature pursuant thereto.

Date: Thursday, December 2, 2021

Autograph:

Printed Name Bradley Tuttle

Address:

From: AmandaLea Boyett
To: DPBH StateBOH
Subject: Comment testimony for 12/3/21 BOH MEETING
Date: Thursday, December 2, 2021 2:56:57 PM

Children's risk of severe illness or death from SARS-COV2 is extremely low. The injury rate of just one of the many adverse events from covid vaccination being tracked by VAERS; myocarditis, is significantly higher than the risk of the disease it is meant to protect children from.
Each current covid vaccine available in the U.S. is under Emergency Use Authorization. The only FDA approved covid vaccine is not currently available to consumers in the U.S.
Parents are responsible to make health and medical choices for their children, and no medical treatment should be coerced or mandated upon children.
Because these vaccines do not prevent infection or transmission of SARS-COV2 but are advertised as a way to reduce symptoms and severity of illness in the injected person, covid vaccination cannot be represented as a "public health" measure which has any effect on anyone but the person injected.

Sincerely,
Amanda Boyett

From: Shannon Gerlits
To: DPBH StateBOH
Subject: Covid vax for NV school children
Date: Thursday, December 2, 2021 1:53:24 PM

Dear NV Board of Health: Dr. J. Pennell, DVM; Dr. J. Murawsky, MD; Dr. T. Larson, MD; Dr. M. Ponce', DDS; Judith Bittner and Charles Smith,

We all want what's best for the children, so I ask you to please take into consideration the data and scientific and medical studies I've shared below on why there should be no Covid-19 vaccine requirements or mandates for children of any age to attend NV schools: The American Heart Association concluding in a publication that the mRNA vacs dramatically increase inflammation on the endothelium and T cell infiltration of cardiac muscle and may account for the observations of increased thrombosis, cardiomyopathy, and other vascular events following vaccination, the BMJ investigating Pfizer for their poorly executed and irresponsible vax trials, the known severe health risks shown in published studies and evidenced in professional athletes, college athletes, and high school athletes around the world developing heart problems and many dying after Covid-19 vax, the most recent known facts from concrete data coming out of Scotland and England where they have been vaxing children 12 and over, and the highly-awarded experts who have come forward with pertinent info, particularly with regard to children!

Please reject all concepts of mandatory Covid shots for school children!

(I placed a red thumbtack next to each post to help identify a new resource.)

the American Heart Association journal, Circulation:
"At the time of this report, these changes persist for at least 2.5 months post second dose of vac.We conclude that the mRNA vacs dramatically increase inflammation on the endothelium and T cell infiltration of cardiac muscle and may account for the observations of increased thrombosis, cardiomyopathy, and other vascular events following vaccination."

Abstract

Our group has been using the PLUS Cardiac Test (GD Biosciences, Inc, Irvine, CA) a clinically validated measurement of multiple protein biomarkers which generates a score predicting the 5 yr risk (percentage chance) of a new Acute Coronary Syndrome (ACS). The score is based on changes from the norm of multiple protein biomarkers including IL-16, a proinflammatory cytokine, soluble Fas, an inducer of apoptosis, and Hepatocyte Growth Factor (HGF)which serves as a marker for

chemotaxis of T-cells into epithelium and cardiac tissue, among other markers. Elevation above the norm increases the PULS score, while decreases below the norm lowers the PULS score.The score has been measured every 3-6 months in our patient population for 8 years. Recently, with the advent of the mRNA COVID 19 vaccines (vac) by Moderna and Pfizer, dramatic changes in the PULS score became apparent in most patients.This report summarizes those results. A total of 566 pts, aged 28 to 97, M:F ratio 1:1 seen in a preventive cardiology practice had a new PULS test drawn from 2 to 10 weeks following the 2nd COVID shot and was compared to the previous PULS score drawn 3 to 5 months previously pre- shot. Baseline IL-16 increased from 35=/-20 above the norm to 82 =/- 75 above the norm post-vac; sFas increased from 22+/- 15 above the norm to 46=/-24 above the norm post-vac; HGF increased from 42+/-12 above the norm to 86+/-31 above the norm post-vac. These changes resulted in an increase of the PULS score from 11% 5 yr ACS risk to 25% 5 yr ACS risk. At the time of this report, these changes persist for at least 2.5 months post second dose of vac.We conclude that the mRNA vacs dramatically increase inflammation on the endothelium and T cell infiltration of cardiac muscle and may account for the observations of increased thrombosis, cardiomyopathy, and other vascular events following vaccination.

https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712

The peer-reviewed British Medical Journal:

The BMJ is a weekly peer-reviewed medical trade journal, published by the trade union the British Medical Association.

BMJ Investigation

Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial

"Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise questions about data integrity and regulatory oversight.

…

But, for researchers who were testing Pfizer's vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at the research organisation Ventavia Research Group has told The BMJ that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided The BMJ with dozens of internal company documents, photos, audio recordings, and emails.

…

Since Jackson reported problems with Ventavia to the FDA in September 2020, Pfizer has hired Ventavia as a research subcontractor on four other vaccine clinical trials (**covid-19**

vaccine in children and young adults, pregnant women, and a booster dose, as well an RSV vaccine trial; NCT04816643, NCT04754594, NCT04955626, NCT05035212). The advisory committee for the Centers for Disease Control and Prevention is set to discuss the covid-19 paediatric vaccine trial on 2 November."

https://www.bmj.com/content/375/bmj.n2635

Why are we vaccinating children against COVID-19?

Especially check out these points:

3.1.3. Potential short-, mid-, and long-term risks of mass COVID-19 inoculation for children

3.1.3.1. Intrinsic inoculant toxicity

3.1.3.2. Adverse inoculant effects on children

3.1.3.2.1. Potential mid-term adverse health effects

3.1.3.2.2. Potential long-term adverse health effects

…both Virginia Stoner [85] and Jessica Rose [86] have shown independently that the deaths following inoculation are not coincidental and are strongly related to inoculation through strong clustering around the time of injection. Our independent analyses of the VAERS database reported in Appendix 1 confirmed these clustering findings.

Additionally, VAERS historically has under-reported adverse events by about two orders-of-magnitude, so COVID-19 inoculation deaths in the short-term could be in the hundreds of thousands for the USA for the period mid-December 2020 to the end of May 2021, potentially swamping the real COVID-19 deaths. Finally, the VAERS deaths reported so far are for the very short term. We have no idea what the death numbers will be in the intermediate and long-term; the clinical trials did not test for those.

The clinical trials used a non-representative younger and healthier sample to get EUA for the injection. Following EUA, the mass inoculations were administered to the very sick (and first responders) initially, and many died quite rapidly. However, because the elderly who died following COVID-19 inoculation were very frail with multiple comorbidities, their deaths could easily be attributed to causes other than the injection (as should have been the case for COVID-19 deaths as well).

Now the objective is the inoculation of the total USA population. Since many of these

potential serious adverse effects have built-in lag times of at least six months or more, we won't know what they are until most of the population has been inoculated, and corrective action may be too late.

sciencedirect.com/science/article/pii/S221475

"Files released by the Food and Drug Administration in a Freedom of Information lawsuit recorded 158,893 adverse events from the Pfizer vaccine in the first two and a half months of distribution, including 25,957 incidents of "nervous system disorders."

The documentation was obtained in a Freedom of Information lawsuit filed a group called Public Health and Medical Professionals for Transparency, comprised of more than 30 professors and scientists from universities including Yale, Harvard, UCLA and Brown.

As WND reported, in court papers filed last week, the FDA proposed that it be given 55 years to release all 329,000 pages of documents related to the Pfizer COVID-19 vaccine requested by the group.

The plaintiffs want the records so they can be assured, amid significant public skepticism, that the Pfizer vaccine is indeed "safe and effective."

Aaron Siri, an attorney for the plaintiffs, argued in court papers filed last week that it is "difficult to imagine a greater need for transparency than immediate disclosure of the documents relied upon by the FDA to license a product that is now being mandated to over 100 million Americans under penalty of losing their careers, their income, their military service status, and far worse."

Siri, who wants the FDA to release all the material no later than March 3, 2022, wrote in a piece published on Substack that the adverse effects were reported in a document titled "Cumulative Analysis of Post-Authorization Adverse Event Reports of [the Vaccine] Received Through 28-Feb-2021."

On page 6 of the document, Pfizer explains: "Due to the large numbers of spontaneous adverse event reports received for the product, [Pfizer] has prioritised the processing of serious cases."

The document says Pfizer "has also taken a [sic] multiple actions to help alleviate the large increase of adverse event reports," including "increasing the number of data entry and case processing colleagues" and "has onboarded approximately [REDACTED] additional fulltime employees (FTEs)."

Siri wants to know why Pfizer, or Justice Department lawyers, blacked out the number of people the pharmaceutical company had to hire "to track all of the adverse events being reported shortly after launching its product."

The attorney said most of the reports of adverse events were from the U.S. and disproportionately involved women -- 29,914 women compared to 9,182 men.

Most were between the ages of 31 and 50 years old, 13,886, compared to 21,325 for all other age groups combined. There were another 6,876 whose ages were unknown.

He noted the 25,957 events classified as "nervous system disorders," with most affecting females between the ages of 30 and 51.

Siri pointed out that that description sounds similar to the vaccine injuries suffered by Brianne Dressen (Part 1, Part 2), Kellai Rodriguez and Suzanna Newell, who testified recently to Republican Sen. Ron Johnson's panel in Washington, D.C.

The attorney noted that Pfizer assured the FDA there was no cause for alarm.

"The findings of these signal detection analyses are consistent with the known safety profile of the vaccine," Pfizer said.

Siri asks: "So if they knew these issues were going to arise, then why didn’t they appear to have enough staff to process this expected volume of reports?"

Pfizer concluded: "The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine."

Whistleblower

Earlier this month, hours before a CDC panel's approval of the Pfizer vaccine for children 5-11, the British Medical Journal published an article featuring a whistleblower's charge that poor practices at a contract research company helping to carry out the crucial third phase of Pfizer's COVID-19 vaccine trial last fall may have compromised data integrity and patient safety.

Members of FDA and CDC advisory panels, in fact, expressed concern that safety data for children regarding Pfizer's COVID vaccine is lacking. Nevertheless, Pfizers CEO charged earlier this month that people are spreading "misinformation" about the vaccines, calling them "criminals" who have cost "millions of lives."

The FDA approved the Pfizer shot for young children one week after an FDA advisory panel voted 17-0, with one abstention, to recommended it, despite acknowledging the lack of safety data and the nearly 100% survival rate for children from infection.

During the FDA advisory committee meeting, Dr. Eric Rubin, editor-in-chief of the New England Journal of Medicine, expressed the concern of many members about possible severe side effects that cannot yet be measured. He concluded, nevertheless, there was no other way forward.

"We're never going to learn about how safe the vaccine is unless we start giving it," he said. "That's just the way it goes."

More than 18,000 deaths attributed to COVID-19 vaccines have been reported to the CDC's Vaccine Adverse Events Reporting System website.

Health and Human Services points out that a VAERS report is not documentation that a link has been established between a vaccine and an adverse event. However, HHS also notes that

VAERS is a "passive" system of reporting, and it "receives reports for only a small fraction of actual adverse events." Many health care workers have disclosed they are instructed by their superiors not to report to VAERS any harm caused by COVID vaccines.

And the website OpenVAERS, which compiles summaries of the data on VAERS, points to an analysis known as the "Lazarus Report," which concluded VAERS represents only 1% of vaccine injuries.

In early October, three Pfizer scientists were captured on hidden camera in a Project Veritas investigation admitting, contrary to the claims of Dr. Anthony Fauci and other public health officials, that natural immunity is superior to the immunity afforded from COVID vaccines.

Project Veritas interviewed an employee of the U.S. Department of Health and Human Services who secretly recorded colleagues voicing alarm about the safety of the vaccines. She alleged a cover-up of "evil at the highest level." In another investigation by Project Veritas, two Johnson & Johnson officials said children don't need the vaccine and it poses the risk of "unknown repercussions down the road."

Pfizer scientist Rahul Khanke said employees are "bred and taught" to insist that the "vaccine is safer than actually getting COVID." He said "we cannot talk about this" in public.“

https://www.wnd.com/2021/11/fda-files-26000-nervous-system-disorders-pfizer-vaccine-first-2-5-months/

HUGE: CDC and Big Pharma Data Confirm that More Children will Die from COVID Vaccine than from the COVID Virus

Dr. Michael Yeadon, former Pfizer VP argued earlier this month [November] that children are 50 times more likely to be killed by the COVID vaccines than the virus itself,”

“The catch is there were 5 heart attack deaths in the vaccine group and only 1 in placebo group. So for every 1 life saved from Covid, the Pfizer vaccine kills 4 from heart attacks. All cause mortality in the 6 month study was 20 in vaccine group and 14 in placebo group. So a 42% all cause mortality increase among the vaccinated. The vaccine loses practically all efficacy after 6 months so they had to curtail the study.”

After noting that Pfizer changed their study parameters when calculating NNTV on children to hide the harms of the vaccine, Rogers shared the following:

All of the NNTV estimates above are based on data from adults. In kids the NNTV will be even higher (the lower the risk, the higher the NNTV to prevent a single bad outcome). Children ages 5 to 11 are at extremely low risk of death from coronavirus. In a meta-analysis combining data from 5 studies, Stanford researchers Cathrine Axfors and John Ioannidis found a median infection fatality rate (IFR) of 0.0027% in children ages 0-19. In children ages 5 to 11 the IFR is even lower. Depending on the study one looks at, COVID-19 is slightly less dangerous or roughly equivalent to the flu in children.

Rogers then lays out the number of individuals that would need to be vaccinated in order to save one child's life from a COVID death:

As of October 30, 2021, the CDC stated that 170 children ages 5 to 11 have died of COVID-19-related illness since the start of the pandemic. (That represents less than 0.1% of all coronavirus-related deaths nationwide even though children that age make up 8.7% of the U.S. population).
The Pfizer mRNA shot only "works" for about 6 months (it increases risk in the first month, provides moderate protection in months 2 through 4 and then effectiveness begins to wane, which is why all of the FDA modeling only used a 6 month time-frame). So any modeling would have to be based on vaccine effectiveness in connection with the 57 (170/3) children who might otherwise have died of COVID-related illness during a 6-month period.
At best, the Pfizer mRNA shot might be 80% effective against hospitalizations and death. That number comes directly from the FDA modeling (p. 32). I am bending over backwards to give Pfizer the benefit of considerable doubt because again, the Pfizer clinical trial showed NO reduction in hospitalizations or death in this age group. So injecting all 28,384,878 children ages 5 to 11 with two doses of Pfizer (which is what the Biden administration wants to do) would save, at most, 45 lives (0.8 effectiveness x 57 fatalities that otherwise would have occurred during that time period = 45).

So then the NNTV to prevent a single fatality in this age group is 630,775 (28,384,878 / 45). But it's a two dose regimen so if one wants to calculate the NNTV per injection the number doubles to 1,261,550. It's literally the worst NNTV in the history of vaccination.

Rogers then goes on to provide an estimate of teh number of children with deadly side effects from taking the COVID vaccine.

Kirsch, Rose, and Crawford (2021) estimate that VAERS undercounts fatal reactions by a factor of 41 which would put the total fatal side effects in this age-range at 5,248. (Kirsch et al. represents a conservative estimate because others have put the underreporting factor at 100.)

Rogers sums it up as follows:

So, to put it simply, the Biden administration plan would kill 5,248 children via Pfizer mRNA shots in order to save 45 children from dying of coronavirus.

For every one child saved by the shot, another 117 would be killed by the shot.

The Pfizer mRNA shot fails any honest risk-benefit analysis in children ages 5 to 11.

More… Dr. Michael Yeadon, former Pfizer VP argued earlier this month that children are 50 times more likely to be killed by the COVID vaccines than the virus itself,"

Yeadon was a chief scientific officer and vice president at Pfizer before he left in 2011 after more than 16 years at the company.

Yeadon also told Steve Bannon earlier this month, "It's a crazy thing to vaccinate (children) with something that is actually 50 times more likely to kill them than the virus itself,"

There is no rational reason for giving children the COVID shot. This is insane.

https://www.thegatewaypundit.com/2021/11/shockingly-insane-cdc-big-pharma-data-show-save-lives-less-50-children-covid-5000-children-will-die-vaccine/

Heart problems in athletes around the world after Covid-19 vax

https://rumble.com/voxcah-athletes-around-the-world-are-dropping-like-flies-with-heart-problems.html

Report: The Fully Vaccinated Account for 81% of the COVID Deaths in the UK

"The report reveals that there were 833,332 recorded Covid-19 cases, 9,094 Covid-19 hospitalisations and 3,700 Covid-19 deaths from October 25th to November 21st. Of these the unvaccinated accounted for 39% of all cases, 34% of all hospitalisations, and 19% of all deaths. Whilst the vaccinated accounted for 61% of all cases, 66% of all hospitalisations, and 81% of all deaths."
***
"According to the latest figures, more than 50 million people have had a first vaccine dose – some 88% of over-12s. More than 46 million – 80% of over-12s – have had both doses.

The Daily Expose reported:

The UK Health Security Agency (UKHSA) publish a weekly 'Vaccine Surveillance' report containing statistics on Covid-19 cases, hospitalisations and deaths by vaccination status across England over the past four weeks.

Their latest report, published Thursday November 25th covers data on infections, hospitalisations and deaths from Week 43 to Week 46 of 2021 (October 25th – November 21st).

The report reveals that there were 833,332 recorded Covid-19 cases, 9,094 Covid-19 hospitalisations and 3,700 Covid-19 deaths from October 25th to November 21st. Of these the unvaccinated accounted for 39% of all cases, 34% of all hospitalisations, and 19% of all deaths. Whilst the vaccinated accounted for 61% of all cases, 66% of all hospitalisations, and 81% of all deaths."

https://www.thegatewaypundit.com/2021/11/report-fully-vaccinated-account-81-covid-deaths-uk/

VIDEO: Former Pfizer Employee Says COVID-19 Vaccine Causes Recipients to Become More Susceptible to the Virus

“A former Pfizer employee, now working as a pharmaceutical marketing expert and biotech analyst, has provided evidence in a public meeting in September suggesting that Pfizer is aware that these shots can cause those vaccinated to be more prone to contracting COVID-19 and infections.

According to the whistleblower, “So, when they weren’t injected, their infection rate was 1.3% and when they got injected, it was 4.34%. It went up by over 300%. They had less infection when they had no protection. So, that’s a problem.”

Kingston said, “if you have two doses of Pfizer, your rate for getting infected [with COVID-19] increases over time.”

Leading to a discovery the biotech analyst called “super alarming,” the report looked exclusively at the placebo group, comparing their rate of infection in the first four months, when they had no protection, to the four months following their injections with the Pfizer product.

During that initial placebo period, the document reports that the infection rate of this group was “12.6 cases per 1,000 person-years,” which equates to a 1.3% infection rate. Following their injections, there were “43.4 cases per 1,000 person- years” or a 4.34% infection rate.

“So, when they weren’t injected, their infection rate was 1.3%, and when they got injected, it was 4.34%. It went up by over 300%,” Kingston observed. “That 300% increase is a correlation, it’s not an anomaly.”

Thus, she summarized, “They had less [COVID-19] infection when they had no protection [from the Pfizer shots]. So, that’s a problem.”

While correlation does not prove causation, looking at relevant global data, we find a worldwide trend of high rates of infections, hospitalizations, and deaths among the vaccinated.

This phenomenon of rising cases occurring in association with high vaccine uptake has become a universal trend while there has also been a correlation between COVID-19 vaccine campaigns and rising death rates from the disease as well.

Summarizing the findings of the Pfizer study in the FDA briefing document itself, Renz explained to his large live and streamed audience, “It says if you get the Pfizer vax, you’re more likely to get COVID. More likely! It says it right there.”

Read more here.
Watch the video of Attorney Thomas Renz as he presents the whistleblower data from ‘never before seen vaccine injury/death tracking system.’

Here’s a video of Karen Kingston as she shares the horrifying truth about COVID-19 vaccine:“

https://www.thegatewaypundit.com/2021/11/video-former-pfizer-employee-says-covid-19-vaccine-causes-recipients-become-susceptible-virus/

FDA Committee Members Reviewing Pfizer Vaccine For Children Have Worked For Pfizer, Have Big Pfizer Connections

This Is A Staggering Conflict of Interest

https://nationalfile.com/fda-committee-members-reviewing-pfizer-vaccine-for-children-have-worked-for-pfizer-have-big-pfizer-connections/

THE UK… 85% of Covid-19 deaths are among the Vaccinated, Child deaths have risen by 83% since they were offered the jab, the Covid-19 Vaccines have negative effectiveness as low as -132%

https://theexpose.uk/2021/11/03/uk-has-fallen-85-percent-covid-deaths-vaccinated-child-deaths-83-percent-higher/

22 Studies and Reports that Raise Profound Doubts about Vaccine Efficacy for the General Population

https://brownstone.org/articles/22-studies-and-reports-that-raise-profound-doubts-about-vaccine-efficacy-for-the-general-population/

Sen. Johnson Expert Panel on Federal Vaccine Mandates - November 2, 2021

Roundtable discussion with vaccine injured and medical experts on federal vaccine mandates and the importance of health care freedom.

https://rumble.com/vokrf7-sen.-johnson-expert-panel-on-federal-vaccine-mandates.html

Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease

“Results of the study
COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the development and testing of these vaccines suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE).

Conclusions drawn from the study and clinical implications

The specific and significant COVID-19 risk of ADE should have been and should be prominently and independently disclosed… in order to meet the medical ethics standard of patient comprehension for informed consent.

…the evidence from the Pfizer, Moderna and Johnson & Johnson…COVID-19 vaccine trials …establishes…the specific risk that receiving the COVID-19 vaccine could convert a subject from someone who experiences mild disease to someone who experiences severe disease…

CONCLUSION
Given the strong evidence that ADE is a non-theoretical and compelling risk for COVID-19 vaccines…disclosure of the specific risk of worsened COVID-19 disease from vaccination calls for a specific, separate, informed consent form and demonstration of patient comprehension in order to meet medical ethics standards….”

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7645850/#!po=84.0909

Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California

https://www.medrxiv.org/content/10.1101/2021.08.19.21262139v1

Three studies published by the CDC, UK Government & Oxford University find the Covid-19 Vaccines do not work

A graduate of Yale University who also obtained a PHD at Princeton University and an MD degree from the John Hopkins University School of Medicine has published a paper in which she concludes that mandating the public to take a vaccine is a harmful and damaging act because of excellent scientific research papers which clearly demonstrate the vaccines do not prevent infection or transmission of Covid-19.
Nina Pierpont (MD, PhD) published a paper on September 9th analysing various studies that were published in August 2021 which prove the alleged Delta Covid-19 variant is evading the current Covid-19 injections on offer and therefore do not prevent infection or transmission of Covid-19.
The Doctor of Medicine explained in her published paperthat vaccines aim to achieve two ends –

1. Protect the vaccinated person against the illness
2. Keep vaccinated people from carrying the infection and transmitting it to others.

However, the Doctor of Medicine writes that herd immunity will not be reached through vaccination because new research in multiple settings shows that the alleged Delta variant produces very high viral loads which are just as high in the vaccinated population compared to the unvaccinated population.
Therefore, according to Nina Pierpont (MD, PhD), vaccine mandates; such as the one now enforced in the UK for all Care Home staff, have no justification because vaccinating individuals does not stop or even slow the spread of the alleged dominant Delta Covid-19 variant.

Which leads the Doctor of Medicine to conclude that natural immunity is much more protective than vaccination because all severities of Covid-19 illness produce healthy levels of natural immunity.
Nine Pierpont (MD, PhD) cites three studies whose findings and data support her conclusions and these include a study published August 6th 2021 in the Centre for Disease Control's (CDC) 'Morbidity and Mortality Weekly Report', another study published August 10th2021 by Oxford University, and a final study published August 24th 2021 which was funded by the UK Department for Health and Social Care.

CDC Study

The CDC study focused on 469 cases among Massachusetts residents who attended indoor and outdoor public gatherings over a two week period. The results found that 346 of the cases were among vaccinated residents with 74% of them presenting with alleged Covid-19 symptoms, and 1.2% being hospitalised.
However the remaining 123 cases were among the unvaccinated population with just 1 person being hospitalised (0.8%. No deaths occurred in either group. The study also found that viral loads were found to be very similar among the vaccinated and unvaccinated, meaning they were equally infectious.

Oxford University Study

The Oxford University study examined 900 hospital staff members in Vietnam who had been vaccinated with the Oxford / AstraZeneca viral vector injection between March and April 2021. The entire hospital staff tested negative for the Covid-19 virus in mid May 2021 however, the first case among the vaccinated staff members was discovered on June 11th.
All 900 hospital staff were then retested for the Covid-19 virus and 52 additional cases were identified immediately, forcing the hospital into lockdown. Over the next two weeks, 16 additional cases were identified.
The study found that 76% of the Covid-19 positive staff developed respiratory symptoms, with 3 staff members developing pneumonia and one staff member requiring three days of oxygen therapy. Peak viral loads among the fully vaccinated infected group were found to be 251 times higher than peak viral loads found among the staff in March – April 2020 when they were not vaccinated.

UK Department of Health & Social Care Study

The UK Department of Health & Social Care study is an analysis of ongoing population wide SARS-CoV-2 monitoring in the UK and includes measures of viral load among the population.
The study found that viral loads among the vaccinated and unvaccinated population are virtually the same, and much higher than had been recorded prior to the Covid-19 injection roll-out. The study also found that the majority of cases among the vaccinated population were presenting with symptoms when they became positive.

The above three studies lead Nina Pierpont (MD, PhD) to conclude in her paper that mandating others to take a vaccine is a potentially harmful, damaging act.
She writes that since the principal reason of a mandate is to protect others from infection, and these studies prove beyond a shadow of a doubt that they do not do this, those who mandate

the Covid-19 injections may wish to seek legal counsel regarding their culpability and liability for potential long-lasting harm to those whom they pressure into vaccination with the threat of exclusion from employment, education or society.

https://theexpose.uk/2021/09/12/three-studies-find-the-covid-19-vaccines-do-not-work/

History of serious problems in all previous SARS coronavirus vaccine trials:

Immunization with SARS coronavirus vaccines leads to pulmonary immunopathology on challenge with the SARS virus
Chien-Te Tseng et al. PLoS One. 2012.

Abstract
Background: Severe acute respiratory syndrome (SARS) emerged in China in 2002 and spread to other countries before brought under control. Because of a concern for reemergence or a deliberate release of the SARS coronavirus, vaccine development was initiated. Evaluations of an inactivated whole virus vaccine in ferrets and nonhuman primates and a virus-like-particle vaccine in mice induced protection against infection but challenged animals exhibited an immunopathologic-type lung disease.

Results: All vaccines induced serum neutralizing antibody with increasing dosages and/or alum significantly increasing responses. Significant reductions of SARS-CoV two days after challenge was seen for all vaccines and prior live SARS-CoV. All mice exhibited histopathologic changes in lungs two days after challenge including all animals vaccinated (Balb/C and C57BL/6) or given live virus, influenza vaccine, or PBS suggesting infection occurred in all. Histopathology seen in animals given one of the SARS-CoV vaccines was uniformly a Th2-type immunopathology with prominent eosinophil infiltration, confirmed with special eosinophil stains. The pathologic changes seen in all control groups lacked the eosinophil prominence.

Conclusions: These SARS-CoV vaccines all induced antibody and protection against infection with SARS-CoV. However, challenge of mice given any of the vaccines led to occurrence of Th2-type immunopathology suggesting hypersensitivity to SARS-CoV components was induced. Caution in proceeding to application of a SARS-CoV vaccine in humans is indicated."

https://pubmed.ncbi.nlm.nih.gov/22536382/

Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens

Could some vaccines drive the evolution of more virulent pathogens? Conventional wisdom is that natural selection will remove highly lethal pathogens if host death greatly reduces

transmission. Vaccines that keep hosts alive but still allow transmission could thus allow very virulent strains to circulate in a population. Here we show experimentally that immunization of chickens against Marek's disease virus enhances the fitness of more virulent strains, making it possible for hyperpathogenic strains to transmit. Immunity elicited by direct vaccination or by maternal vaccination prolongs host survival but does not prevent infection, viral replication or transmission, thus extending the infectious periods of strains otherwise too lethal to persist. Our data show that anti-disease vaccines that do not prevent transmission can create conditions that promote the emergence of pathogen strains that cause more severe disease in unvaccinated hosts.

Author Summary

There is a theoretical expectation that some types of vaccines could prompt the evolution of more virulent ("hotter") pathogens. This idea follows from the notion that natural selection removes pathogen strains that are so "hot" that they kill their hosts and, therefore, themselves. Vaccines that let the hosts survive but do not prevent the spread of the pathogen relax this selection, allowing the evolution of hotter pathogens to occur. This type of vaccine is often called a leaky vaccine. When vaccines prevent transmission, as is the case for nearly all vaccines used in humans, this type of evolution towards increased virulence is blocked. But when vaccines leak, allowing at least some pathogen transmission, they could create the ecological conditions that would allow hot strains to emerge and persist. This theory proved highly controversial when it was first proposed over a decade ago, but here we report experiments with Marek's disease virus in poultry that show that modern commercial leaky vaccines can have precisely this effect: they allow the onward transmission of strains otherwise too lethal to persist. Thus, the use of leaky vaccines can facilitate the evolution of pathogen strains that put unvaccinated hosts at greater risk of severe disease. The future challenge is to identify whether there are other types of vaccines used in animals and humans that might also generate these evolutionary risks.

Citation: Read AF, Baigent SJ, Powers C, Kgosana LB, Blackwell L, Smith LP, et al. (2015) Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens. PLoS Biol 13(7): e1002198. doi:10.1371/journal.pbio.1002198
Academic Editor: Christophe Fraser, Imperial College London, UNITED KINGDOM

Received: January 15, 2015; **Accepted:** June 11, 2015; **Published:** July 27, 2015

https://journals.plos.org/plosbiology/article/info:doi/10.1371/journal.pbio.1002198

Meet 15 Heroes of the Pandemic - Over 9,100 medical doctors and scientists have signed a document charging policy-makers with potential "crimes against humanity"

Over 9,100 medical doctors and scientists have signed a document charging policy-makers with potential "crimes against humanity," accusing them of preventing physicians from providing life-saving treatments for their patients and suppressing open scientific discussion.
…

A year ago, more than 860,000 infectious disease epidemiologists and public health scientists

signed a declaration expressing their "grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies."
The Great Barrington Declaration argued that "the most compassionate" way to reach herd immunity while minimizing mortality and social harm was "to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk."
…
Among the detractors of this narrative, highlighted below, are medical doctors, infectious-disease researchers, virologists, a former vice president of Pfizer, the inventor of mRNA vaccine technology, and even a state surgeon general.

Analysis from the Vaccine Adverse Event Reporting System (VAERS) data shows that over a half a million people have had adverse effects from the vaccines, including life-threatening reactions, permanent disability, birth defects, and death. For a variety of reasons, (e.g. deliberate suppression of the truth, laziness) it is widely believed that only a small fraction of adverse events actually get reported into the system. A 2011 study by Harvard Pilgrim Health Care, for instance, found that the number could be as low as one percent.
Forty-five years ago, the federal government pulled a vaccine that caused only a tiny fraction of the number of adverse reactions that are being reported today.
In 1976, three states halted the Swine Flu vaccineafter only three deaths. Later that year, the CDC pulled the vaccine from the market entirely after about 500 people developed a rare neurological condition called Guillain-Barré syndrome, and about 25 people died.
The number of COVID vaccine casualties in 2021 eclipsed those numbers in the first month.
…
https://amgreatness.com/2021/10/02/heroes-of-the-pandemic/

Pfizer's Comirnaty is not available in the USA, only the EUA version, which protects Pfizer from lawsuits and leaves all vaccine injured with no recourses or help:

"Between the manipulation by big pharma and the media, the major conflict of interest with the FDA voting panel and Pfizer, FDA's bait-and-switch on the approval process of Comirnaty, the Biden regime threatening the country to get an EUA jab against their will, and the hundreds of thousands of global adverse events and deaths reported after receiving the jabs, this should all be a huge red flag for anyone considering getting the jab or having their children get the jab."

NEW ARTICLE with important information and evidence:

Pfizer-Connected FDA Panel Approves Pfizer EUA Covid Jab for Children 5-11 While Comirnaty Remains Unavailable and IA2030 Push for Life-Course Vaccines for All

https://www.coreysdigs.com/health-science/pfizer-connected-fda-panel-approves-pfizer-eua-covid-jab-for-children-5-11-while-comirnaty-remains-unavailable-and-ia2030-push-for-life-course-vaccines-for-all/

Pfizer Fail to Perform industry Standard Animal Testing Prior to Initiation of mRNA Clinical Trials
Source: EMA

https://trialsitenews.com/did-pfizer-fail-to-perform-industry-standard-animal-testing-prior-to-initiation-of-mrna-clinical-trials/

How Moderna Rigged Its COVID-19 Vaccine Trials To Falsely Show Effectiveness

https://greatmountainpublishing.com/2021/02/27/how-moderna-rigged-its-covid-19-vaccine-trials-to-falsely-show-effectiveness/

Covid variant injections are to be marketed without safety trials, Fauci confirmed it, and that antibodies/antigens to SARS-CoV-2 are found in saliva, making the use of masks counterproductive in achieving herd immunity.

https://rumble.com/vf5vsj-no-clinical-trials-for-vaccines.-fauci-confirms..html

2019 - Fauci and his HHS peeps in 2019 explaining how time-consuming RNA vaccine trials are, and how if only some "urgent call" that's "not beholden to bureaucratic strings and processes" could come along they could introduce the vaccine more easily

Host: Why don't we blow this system up? I mean, obviously we can't just turn off the spigot on the system we have and then say "hey, everyone in the world should get this new vaccine we haven't given to anyone yet." But there must be some way. We grow vaccines mostly in eggs the way we did in 1947.

Fauci: In order to make the transition from getting out of the tried and true egg growing, which we know gives us results that can be, you know, beneficial—I mean we've done well with that—to something that has to be much better, you have to prove that this works, and then you've got to go through all of the clinical trials—phase ones, phase twos, phase three—and then show that this particular product is going to be good over a period of years. That alone, if it works perfectly, is going to take a decade.

HHS BARDA Director Rick Bright: To make it sexy I think we have to, I like the concept of disrupting this field. There might be a need, or even an urgent call for an entity of excitement out there that's completely disruptive, that's not beholden to bureaucratic strings and processes.

Fauci: So we really do have a problem of how the world perceives influenza, and it's going to be very difficult to change that unless you do it from within and say "I don't care what your perception is, we're going to address the problem"—in a disruptive way and in an iterative way, because you do need both.

Rick Bright: But it is not too crazy to think that an outbreak of a novel avian virus could occur in China somewhere. We could get the RNA sequence from that, beam it to a number of regional centers, if not local, if not even in your home at some point, and print those vaccines on a patch and self-administer.
https://youtu.be/5gD2hbTF3qw

Fauci, Bill Gates, Gates Foundation, GSK's [Glaxo Smith Kline's], Wuhan Institute of Virology, China, China FDA, US FDA, NIAID:

New Fauci Emails
https://www.judicialwatch.org/press-releases/new-fauci-emails/

2018. Bill Gates' INSTITUTE FOR DISEASE MODELING released a video modeling a pandemic starting at Wuhan, China
The Gates Foundation released an animation April 27, showing what would occur if a highly contagious airborne pathogen, like the 1918 flu, would happen today. (Institute of Disease Modeling and Bill & Melinda Gates Foundation)
Bill Gates calls on U.S. to lead fight against a pandemic that could kill 33 million

https://www.washingtonpost.com/news/to-your-health/wp/2018/04/27/bill-gates-calls-on-u-s-to-lead-fight-against-a-pandemic-that-could-kill-millions/

Sept. 2021: Ivermectin: a multifaceted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, COVID-19

https://www.sciencedirect.com/science/article/pii/S2052297521000883

Abstract:"In 2015, the Nobel Committee for Physiology or Medicine, in its only award for treatments of infectious diseases since six decades prior, honoured the discovery of ivermectin (IVM), a multifaceted drug deployed against some of the world's most devastating tropical diseases. Since March 2020, when IVM was first used against a new global scourge, COVID-19, more than 20 randomized clinical trials (RCTs) have tracked such inpatient and outpatient treatments. Six of seven meta-analyses of IVM treatment RCTs reporting in 2021 found notable reductions in COVID-19 fatalities, with a mean 31% relative risk of mortality vs. controls. During mass IVM treatments in Peru, excess deaths fell by a mean of 74% over 30 days in its ten states with the most extensive treatments."

Feb. 2017: Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations

https://www.nature.com/articles/ja201711

Feb. 2011: Ivermectin, 'Wonder drug' from Japan: the human use perspective

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043740/#__ffn_sectitle

I-MASK+ Prevention and Early Outpatient Treatment Protocol for Covid-19
Current I-MASK+ protocol: version 12, updated on August 11, 2021 (English version, translations follow).

https://covid19criticalcare.com/covid-19-protocols/i-mask-plus-protocol/

71 out of 75 Districts in Uttar Pradesh, India - Its Most Populated State - Reported No Covid-19 Cases in 24 Hours After Implementing Ivermectin Protocol

https://www. https://www.thegatewaypundit.com/2021/10/update-71-75-districts-uttar-pradesh-india-reported-no-covid-19-cases-24-hours-implementing-ivermectin-protocol/

Dr. Fauci pushed the use of Veklury® (remdesivir) as a treatment for COVID-19 knowing that it would be unsafe and ineffective for patients.

Veklury® (remdesivir) is a nucleotide analogue RNA polymerase inhibitor. Dr. Ardis reveals that the symptoms of lungs filling with fluid and the other alleged COVID-19 symptoms were actually side effects of kidney poisoning and other organ damage that are known side-effects of Veklury® (remdesivir). Dr. Ardis alleges that the devestating health toll allegedly caused by COVID-19 was actually caused by the NIH recommended treatment of Veklury® (remdesivir).

Dr. Bryan states that the NIH even cited two studies on its website that showed that Veklury® (remdesivir) was ineffective and unsafe to patients.

NIH Recommends Remdesivir
On May 12, 2020, the NIH recommended the use of Veklury® (remdesivir) for severe cases of COVID-19. At that time, Veklury® (remdesivir) was an unapproved experimental drug made by Gilead Sciences. It was authorized by the FDA for emergency use treatment of COIVD-19.

Conflicts Of Interest
The recommendation from the NIH to use Veklury® (remdesivir) to treat COVID-19 came from the NIH Panel on COVID-19 Treatment Guidelines. There were nine (9) people on the NIH Panel on COVID-19 Treatment Guidelines with financial ties to Gilead Sciences, the maker of Veklury® (remdesivir).
Steering Doctors Away From Hydroxychloroquine

The panel tried to steer doctors away from Hydroxychloroquine, by stating that "[t]here are insufficient clinical data to recommend either for or against using chloroquine or hydroxychloroquine for the treatment of COVID."

The panel, of course, had an interest in undermining inexpensive and effective treatements: "[T]he Panel recommends against the use of the following drugs for the treatment of COVID-19: The combination of hydroxychloroquine plus azithromycin because of the potential for toxicities." That was not true. Indeed many subsequent studies have shown that the hydroxychloroquine plus azithromycin "combination is safe and may avoid worsening, virus persistence, and subsequent contagiosity."

Remdesivir Adverse Events
Many of the studies cited in support of NIH's recommendation to use Veklury® (remdesivir) were in vitro studies or animal studies. A couple of the human studies were at best a mixed bag. Two of the most authoritative studies showed Veklury® (remdesivir) to be ineffective and unsafe.

Please do not miss the fact that there were reported 71 percent adverse events in the 5-day study and 74 percent adverse events in the 10-day study for patients taking Veklury® (remdesivir). 21 percent suffered serious adverse events in the 5 day study and 35 percent of the patients suffered serious adverse events in the 10-day study.

Majority Of Patients On Remdesivir Suffer Liver Damage
Amazingly, in the May 2020 FDA publication indicated that a majority of the participants in the several remdesivir studies conducted have suffered liver damage.

Kidney Damage From Remdesivir Is Foreseeable

Another foreseeable side effect of Veklury® (remdesivir) is kidney damage. The FDA pubication reveals that "[i]ntravenous administration (slow bolus) of remdesivir to rats at dosage levels of =3 mg/kg/day for up to 4 weeks resulted in findings indicative of kidney injury and/or dysfunction."

Invasive Mechanical Ventilation Required

In another later published study (ACTT-1, NCT04280705) reported in the October 10, 2010 FDA emergency use auhthorization that alleged to show the benefits of Veklury® (remdesivir), 27 percent of the patients taking Veklury® (remdesivir) "were on invasive mechanical ventilation." There was no control group in that study. It seems that the ventilation was the result of Veklury® (remdesivir) because the study revealed that "[s]ubjects on mechanical ventilation at screening were excluded" from the study.

Early Study Termination Due To Adverse Events

In another human study conducted in China, 12 percent of the Veklury® (remdesivir) group participants had to discontinue therapy with Veklury® (remdesivir) due to adverse side effects. That compared to 5 percent in the control group.

Remdesivir Proven Ineffective In Ebola Study
There was only one other human study cited, and the results were devastating for the patients in that study who were administered Veklury® (remdesivir). In that study, Veklury® (remdesivir) was compared to three other treatments for Ebola. The control group was not actually a placebo group. The group was administered a medicine identified as ZMapp (a triple monoclonal antibody agent).
Veklury® (remdesivir) had the highest mortality of any of the treatment modalities with 53.1 percent of the Ebola patients who were administered Veklury® (remdesivir) dying within 28 days.

Yet, with those studies showing the Veklury® (remdesivir) is unsafe and ineffective, the NIH recommended Veklury® (remdesivir) as the treatment for COVID-19. The results were foreseeable. Its use to treat patients with COVID-19 were predictably ineffective and unsafe.

https://principia-scientific.com/doctor-reveals-remdesivir-is-real-cause-of-covid-19-maladies/

Reuters reports: "Four people in southern Germany have tested positive for the

Omicron COVID-19 variant even though they were fully vaccinated against the coronavirus, the public health office in the state of Baden-Wuerttemberg said."

https://summit.news/2021/12/01/germany-detects-four-cases-of-omicron-in-the-fully-vaccinated/

All Four Batswana "Nu" variant patients were fully vaccinated

Thank you for taking the time to read what I have researched. We all want what's best for the kids. Let's do right by them and not mandate these vaccines!

Sincerely,
Shannon Gerlits

Sent from my iPhone

From: JULIE ADAMS
To: DPBH StateBOH
Subject: Immunization for Children
Date: Thursday, December 2, 2021 1:53:11 PM

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Dr. Jon Pennell, DVM; Dr. Jeffrey Murawsky, MD; Dr. Trudy Larson, MD; Dr. Monica Ponce', DDS; Judith Bittner and Charles Smith,

Science is being ignored, children are not at risk for Covid. When have we as a society put our children out to "protect the adults"? We are to protect them. The many adverse effects of these "vaccines" are also being ignored by the Physicians who has sworn to do no harm.

I am contacting you today about any current or future consideration by the Nevada Board of Health to require that children receive COVID vaccines as a requirement for school enrollment and attendance in the state of Nevada. I strongly oppose any such measure and remind you that these vaccines are currently not approved for uptake in children ages 5-17 by the United States Food and Drug Administration (FDA); rather they have been authorized by the FDA under an Emergency Use Authorization (EUA). Per federal law as referenced below, any product licensed under an EUA requires that citizens and therefore in the case of minor children, their parents/legal guardians, have the option to accept or refuse the product.Emergency Use Authorization of Medical Products and Related Authorities Guidance for Industry and Other Stakeholders January 2017

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authoritiesSection E: Conditions of Authorization; 1. Information relating to the EUA Product; b. Information for Recipients: “the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances…….That they have the option to accept or refuse the EUA product”



Emergency Use Authorization of Medical Products

Explains FDA's general recommendations and procedures applicable to authorization of the emergency use of certai...

Best Regards,
Julie Adams

From: Jennifer McCaffrey
To: DPBH StateBOH
Subject: COVID therapies for Children
Date: Thursday, December 2, 2021 1:53:05 PM

Dear Dr. Jon Pennell, DVM; Dr. Jeffrey Murawsky, MD; Dr. Trudy Larson, MD; Dr. Monica Ponce', DDS; Judith Bittner and Charles Smith ~

I am writing to you as a concerned citizen, mother of three, and practicing Pediatric Nurse Practitioner.

I am extremely concerned about any current or future consideration of mandating Covid 19 therapies for school attendance and/or any school-related activities.

All of the currently available therapies (including Pfizer) have not been fully FDA licensed for use in adults or children and remain under the ongoing Emergency Use Authorization (EUA).

Some erroneously believe that Pfizer's BioNTech therapy has been licensed. However, that is not the case. The therapy from Pfizer's German counterpart, the licensed product named COMIRNATY, has been FDA approved. This is not available in our country and per my understanding, will not be available in the United States for two or three more years. Further, these two products have been ruled NOT interchangeable by Federal Courts just this week.

As such, all currently available EUA therapies - Pfizer, Moderna, J&J - must be administered with fully informed and written consent of a legal-age adult, or legal guardian of any minor child. **Per federal law referenced below, any product licensed under an EUA requires that citizens and therefore in the case of minor children, their parents/legal guardians, have the legal right to accept or refuse the product**.

Emergency Use Authorization of Medical Products and Related Authorities Guidance for Industry and Other Stakeholders January 2017https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities
Section E: Conditions of Authorization; 1. Information relating to the EUA Product; b. Information for Recipients: “the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances...That they have the option to accept or refuse the EUA product”.

Mandating biologic products which have not been fully tested, licensed, and proved as safe and effective in a target population (in this case minors under 18 years) would not only fly in the face of typical scientific protocols, but could very well incur medical liability for potential harms resulting from administering **experimental therapies** to children.

Thank you for your sincere consideration of this matter,

Jenny L. Cole, APRN

From:	L Robinson
To:	DPBH StateBOH
Subject:	Public Comment Testimony for 12/3/21 BOH Meeting
Date:	Thursday, December 2, 2021 11:50:14 AM

To the State Board of Health Members:

I oppose covid vaccine mandates or requirements of any sort for all Nevadans. Each of the covid vaccines (Pfizer-Bio-NTech, Moderna and Johnson & Johnson) currently available in the United States are authorized under Emergency Use Authorization by the Food & Drug Administration (FDA). Per federal law, EUA products cannot be mandated, require informed consent and can be declined. The single FDA approved covid vaccine (Pfizer Comirnaty) is not currently available to consumers in the U.S.
I oppose covid vaccine mandates or requirements for children 0-18. Children's risk of severe illness or death from SARS-COV2 is extremely low. The injury rate of just one of the many adverse events from covid vaccination being tracked by VAERS; myocarditis, is significantly higher than the risk of the disease it is meant to protect children from. As parents we are responsible to make health and medical choices for our children, and no medical treatment should be coerced or mandated upon them.

Thank you for your time.
L Robinson

From:	Khanh W
To:	DPBH StateBOH
Date:	Thursday, December 2, 2021 7:58:27 PM

I am very concerned about a mandate for children to get the vacination. There has been no long term studies how this affects children and they are not high risk. It is disturbing that anyone would force such a risk on children. Especially since many may have other health concerns that would make it even more risky. Thank you for taking into account the concerns I am expressing. Please do not mandate this with children.

Action Item #4 - Variance Case #728 Cameron Rose

Wednesday, December 1, 2021 3:21 PM

It sounds like Cameron may have had a former addiction and that he may be reliant on student housing for shelter. He is also on disability income. Did anyone bother to ask him about that while you were playing God with his life?

By the way have you read the recent court ordered Pfizer trial release November 23rd? I attached a copy of the excerpt for you on my email submission. Did you know that they had 93,473 adverse events reported, 1,223 fatalities and 1,927 individuals got COVID from the vaccine trials … and Pfizer knew all of this in February of 2021. And that was just Pfizer's trial. We have not seen Moderna or J & J. If I were you, I would not want that blood on my hands.

So Mr. Azzam stated that COVID has "Killed 7,850 NV residents" - According to CDC Deaths under the age 45 attribute to **4.1% of the nationwide deaths.** That's 322 deaths under 45 in Nevada through the pandemic period. Since the CDC always makes it so difficult to get actual numbers by age ranges I had to divide that by average death per age year which equals 7.1555. Multiply now 7.1555 for a 14 year range of average college 17-30. So 14 years x 7.1555 equals 101 deaths in the approximate college age range. (If these numbers are even correct due to the bonus payments from CMS for positive COVID case reporting) And we have no idea if any of these had diabetes, cancer, hypertension or any other underlying condition. We also don't even know how many were even college students.

So t**he fact that Nevada even passed this sweeping mandate unanimously for over 107,000 college students in the entire state with these numbers tells me NOT ONE of you are doing your own research or you just don't care because there is some alternate benefit or agenda for you personally because it is blatantly non sensical as you would save more lives removing bad food and mandating exercise.**

Mr. Azzam - "Vaccine is very effective and "safe" in reducing and preventing severe infections, hospitalizations and death" NO IT IS DOES NOT PREVENT SEVERE INFECTION OR HOSPITALIZATION OR DEATH. THE REPORT FROM SNHD JUST SAID THERE WERE MULTIPLE DEATHS IN THE VACCINATED. SO, NOT EFFECTIVE OR SAFE FOR EVERYONE AND DO YOU KNOW WHO WILL HAVE AN ADVERSE EFFECT WHEN YOU ARE BLANKETING THESE MANDATES?

CDC and D.r Fauci have told us now that the vaccine does not stop the spread or the contraction of the virus.
Men in particular are at risk of myocarditis and pericarditis per FDA. There are athletes that are collapsing from heart issues and getting blood clots.

This vaccine could cause exceptional undue hardship for Cameron by giving him myocarditis, maiming him with Gullian Barre or any of the other 30,000 other adverse issues reported on VAERS. Hundreds of other pharmaceuticals have been pulled from the market for less than 100 deaths. So really the question is, why do you all want this shot in people so badly?

Cameron should not be asking for a Variance, he should be suing you in the mass lawsuit that is currently being compiled. (By the way Contact Joey Gilbert in Reno Cameron) You should also be recognizing natural immunity.
I have emailed studies on that as well from Harvard etc. Cameron would also have a greater chance of becoming a detriment to society should you force him out of school. He is better off for the overall well being of our society to finish school..

NAC 441A 755 should be eradicated it is ridiculous anyway as it states "proof of immunity" required, no

one in the world can provide that first of all and we all know this vaccine does not make anyone IMMUNE. Your mandate is a violation of the constitution and higher courts are currently making these rulings as we speak. Attorneys in Nevada are chomping at the bit. You will all get paid regardless, but the public will soon know you all participated in this against Nuremberg Code due to this being a trial and experimental which it says right on Pfizer, Moderna and J&J web sites that these shots are NOT FDA approved.

My suggestion is to Give ALL students that do not want this vaccine a Variance if that's all you got and God Bless this young man for trying to go to school on disability income and with no place to live where is your soul?



Elizabeth Hammack - Henderson, NV

  proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

  - In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

  - An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

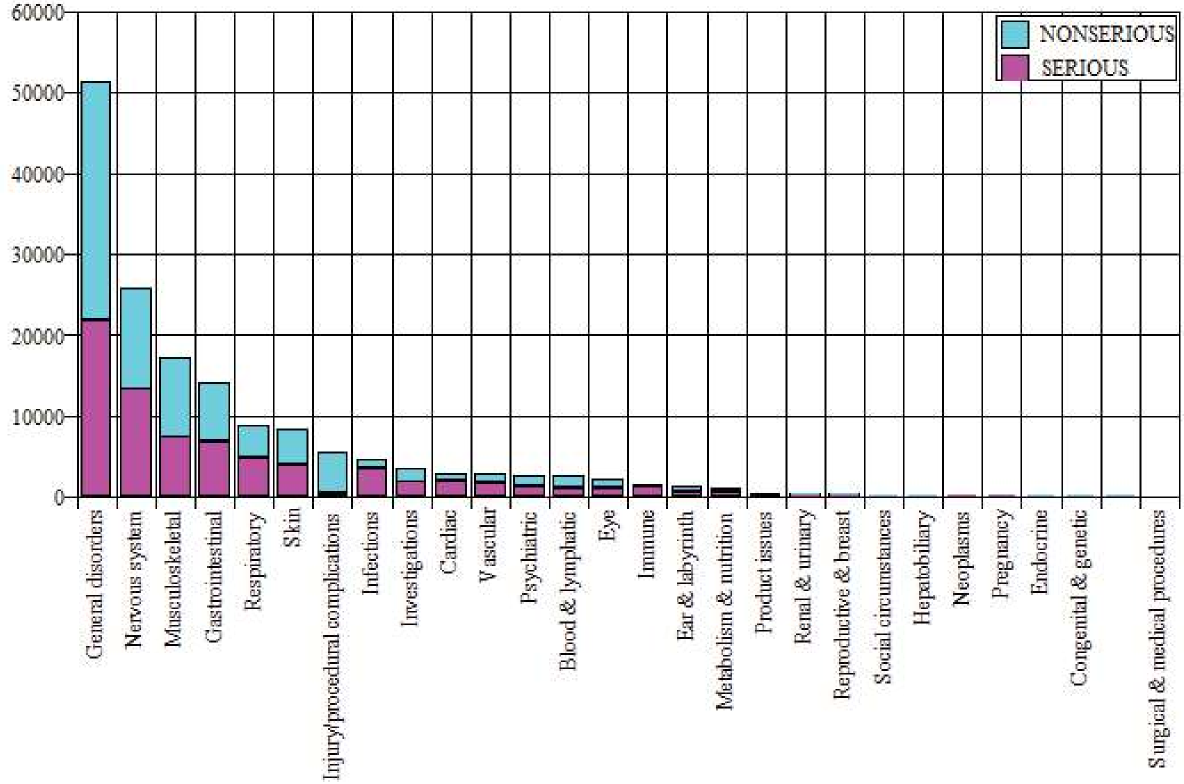


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

MedDRA SOC	MedDRA PT	Cumulatively Through 28 February 2021 AEs (AERP%) N = 42086
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 2. Events Reported in ≥2% Cases

MedDRA SOC	MedDRA PT	Cumulatively Through 28 February 2021 AEs (AERP%) N = 42086
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

Countermeasures Injury Compensation Program (CICP) Data

Aggregate Data as of October 1, 2021

The Countermeasures Injury Compensation Program (CICP) provides compensation for covered serious injuries or deaths that, based on compelling, reliable, valid, medical and scientific evidence, are found to be directly caused by the administration or use of a covered countermeasure or are determined to meet the requirements of a countermeasure injury table. Temporal association between administration or use of the covered countermeasure and onset of the injury (i.e., the injury occurs a certain time after the administration or use) is not sufficient, by itself, to prove that an injury is the direct result of a covered countermeasure.

It is important to note that the CICP data only captures the alleged countermeasure(s) and the alleged injuries that CICP requesters list on their Request for Benefits forms (RFB) or claim. The countermeasure or injury listed by the requester on the RFB may or may not be consistent with the requester's medical documentation or the injury resulting in compensation. While requesters are required to identify the alleged countermeasure on their RFB form, they are not required to list the specific manufacturer or trade name on their RFB form.

Furthermore, while requesters must submit their RFB form within 1 year from the administration or use of the covered countermeasure, requesters are permitted to submit the necessary medical records and other documentation, such as a copy of a requester's COVID-19 vaccination record, after the RFB is filed. For the majority of COVID-19 countermeasure claims, including COVID-19 vaccine claims, the CICP is still waiting for records and documentation to be submitted.

When was the first CICP claim filed?

The first CICP claim was filed in Fiscal Year (FY) 2010; there are no CICP claims to report on prior to FY 2010.

Is the CICP data available by specific manufacturer or trade name?

The CICP does not maintain its aggregated data concerning alleged countermeasures, including vaccines, by specific manufacturer.

How many claims has the CICP compensated?

The CICP is the payer of last resort and can only reimburse or pay for medical expenses or lost employment income that are not covered by other third-party payers. To date, the CICP has paid compensation for 29 CICP claims, totaling more than $6 million. An additional 10 CICP claims were eligible for compensation after a review of the required medical records and documentation; however, in these cases there were no eligible reported medical expenses or lost employment income for the CICP to compensate.

Has the CICP made any decisions regarding COVID-19 Claims?

As of October 1, 2021, the CICP has not compensated any COVID-19 countermeasures claims. Three COVID-19 countermeasures have been denied compensation because the standard of proof for causation was not met and/or a covered injury was not sustained. One COVID-19 claim has been determined eligible for compensation and is pending a review of eligible expenses.

CICP Data for Fiscal Years 2010 – 2021 (As of October 1, 2021)

Total CICP Claims Filed: **3,649**

- Claims Eligible for Medical Review: **3,556**
  - Eligible for Compensation: **40**
    - Compensated: **29**
    - No Eligible Reported Expenses: **10**
    - Pending: **1**
  - Pending Review or In Review: **3,154**

- Denied: **362**
  - Requested Medical Records not Submitted: **135**
  - Standard of Proof Not Met and/or Covered Injury not Sustained: **227**
- Claims Ineligible for Medical Review: **93**
  - Missed Filing Deadline: **38**
  - Not CICP Covered Product/ Not Specified: **55**

CICP claims data is provided below in categories pertaining to their status.

Table 1. Alleged COVID-19 Countermeasure Claims Filed as of October 1, 2021

This table displays the alleged countermeasure and alleged injury/death for each COVID-19 countermeasure claim filed as of October 1, 2021. Of the 3,158 COVID-19 countermeasure claims 1,357 allege injuries/deaths from COVID-19 vaccines and 1,801 allege injuries/deaths from other COVID-19 countermeasures.

The CICP does not maintain its aggregated data concerning alleged countermeasures, including vaccines, by specific manufacturer or trade name.

Alleged Countermeasure	Alleged Injury/ Death	Number of Claims
Failure to have infection control programs in place, the failure to have adequate infection control in place, the failure to properly train staff, the failure to provide sufficient staff, the failure to cohort infected and uninfected individuals, the failure to provide PPE to staff and residents, the failure to train on the proper use of PPE, the failure to have adequate procedures in place to deal with infection, the failure to adequately monitor residents for signs of infection, the failure to transfer residents to a higher level of care when needed, the failure to adequately treat residents with COVID, the failure to provide appropriate distancing among residents, the failure to properly report the number of COVID-19 cases and deaths to authorities, and others.	Death	296
Anakinra	Death	1
Antiviral	Death	1
Azithromycin	Death	12
Azithromycin / BiPAP / Ivermectin / Remdesivir	Death	1
Azithromycin / Cefdinir / G-Tube	Death	1
Azithromycin / Cefdinir/ Ibuprofen	Death	1
Azithromycin / Ceftriaxone / Plaquenil	Death	1
Azithromycin / CiPAP	Death	1
Azithromycin / CiPAP / BiPAP	Death	1
Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir	Death	1
Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir / Solu-Medrol	Death	1

Azithromycin / Convalescent Plasma / Hydroxychloroquine / Ivermectin	Death	1
Azithromycin / Dexamethasone / Remdesivir	Death	1
Azithromycin / Dexamethasone / Steroid	Death	1
Azithromycin / Dialysis / Methylprednisolone	Death	1
Azithromycin / Hydroxychloroquine	Death	10
Azithromycin / Hydroxychloroquine / BiPap / Heparin	Death	1
Azithromycin / Hydroxychloroquine / Bolus / Ceftriaxone / Zosyn	Death	1
Azithromycin / Hydroxychloroquine / Dexamethasone	Death	1
Azithromycin / Hydroxychloroquine / Dialysis	Death	1
Azithromycin / Hydroxychloroquine / Dialysis / Solu-Medrol / Tocilizumab	Death	1
Azithromycin / Hydroxychloroquine / Fentanyl / intubation	Death	1
Azithromycin / Hydroxychloroquine / Intubation	Death	5
Azithromycin / Hydroxychloroquine / Methylprednisolone / Tocilizumab	Death	1
Azithromycin / Hydroxychloroquine / Remdesivir	Death	1
Azithromycin / Hydroxychloroquine / Respirator	Death	1
Azithromycin / Hydroxychloroquine / Rocephin	Death	1
Azithromycin / Hydroxychloroquine / Solu-Medrol	Death	1
Azithromycin / Hydroxychloroquine / Solu-Medrol / Steroids	Death	1
Azithromycin / Ivermectin / Methylprednisolone	Death	1
Azithromycin / Ivermectin / Methylprednisolone / Remdesivir	Death	22
Azithromycin / Metoprolol	Death	1
Azithromycin / Ondansetron / Cefdinir	Death	1
Azithromycin / Remdesivir	Death	5
BiPap / Convalescent Plasma / Remdesivir	Death	1
BiPap / COVID-19 Medications / Nebulizer	Death	1
BiPAP / CPAP / COVID-19 Medications	Death	1
BiPAP / High Flow Oxygen / Remdesivir	Death	1
BiPap / Hydroxychloroquine / Doxycycline / Ceftriaxone / Heparin	Death	1
BiPAP / Hydroxychloroquine / Ivermectin	Death	1
BiPAP / Hydroxychloroquine / Ivermectin / Remdesivir	Death	3
BiPap / Hydroxychloroquine / Remdesivir	Death	1
BiPAP / Ivermectin / Remdesivir / Vapotherm	Death	1

Chest Compression / Epinephrine / Intubation	Death	1
Chest Compressions / Epinephrine	Death	1
Contrast	Kidney Injury	1
Convalescent Plasma	Death	4
Convalescent Plasma / Remdesivir	Death	4
Convalescent Plasma / Tocilizumab / Zithromax	Death	1
COVID-19 Antivirals / Antibiotics / Anti-inflammatory Medications / Oxygen Therapy	Death	1
COVID-19 Infection	Death	1
COVID-19 Medications	Death	10
COVID-19 Medications / Intubation	Death	1
COVID-19 Medications / Remdesivir	Death	1
COVID-19 Test	Death	1
COVID-19 Test	Perforated Ethymoidal Artery	1
COVID-19 Test	Punctured Brain / CSF	1
COVID-19 Test / Heparin / Supplemental Oxygen / Ultrasound (Duplex)	Brain Injury / Quadriplegia	1
COVID-19 Test / Oxygen	Death	1
COVID-19 Vaccine	Abdominal Pain	2
COVID-19 Vaccine	Abdominal Pain / Chills / Lightheadedness	1
COVID-19 Vaccine	Abdominal Pain / Diarrhea / Nausea / Vomiting / Bloating	1
COVID-19 Vaccine	Abdominal Pain / Leg Pain	1
COVID-19 Vaccine	Abdominal Pain / Muscle and Joint Pain / Chills / Vision Distortion / Retina Puckering	1
COVID-19 Vaccine	Aches / Dehydration / Vomiting	1
COVID-19 Vaccine	Acute Brain Disorder	1
COVID-19 Vaccine	Acute Congestive Heart Failure / Kidney Damage	1
COVID-19 Vaccine	Acute Hearing Loss	1
COVID-19 Vaccine	Acute Inflammatory Demyelinating Polyneuropathy	1
COVID-19 Vaccine	Acute ITP	1

COVID-19 Vaccine	Acute Kidney Injury	1
COVID-19 Vaccine	Acute Non-traumatic Kidney Injury / Pericardial Effusion / Elevated AST	1
COVID-19 Vaccine	Acute Pancreatitis	1
COVID-19 Vaccine	Acute Renal Failure / Rhabdomyolsis / Myositis	1
COVID-19 Vaccine	Acute Saddle Pulmonary Embolism	1
COVID-19 Vaccine	Addison's Disease Crisis	1
COVID-19 Vaccine	Adhesive Capsulitis	2
COVID-19 Vaccine	Adverse Reaction	2
COVID-19 Vaccine	AIDP / GBS	1
COVID-19 Vaccine	Allergic Reaction	44
COVID-19 Vaccine	Allergic Reaction / Burns on Skin	1
COVID-19 Vaccine	Allergic Reaction / Hypersensitivity	1
COVID-19 Vaccine	Allergic Reaction / Panic Attack	1
COVID-19 Vaccine	Allergic Reaction / Peripheral Neuropathy	1
COVID-19 Vaccine	Allergic Reaction / Tachycardia	1
COVID-19 Vaccine	Alopecia Areata	1
COVID-19 Vaccine	Anaphylactic Reaction	10
COVID-19 Vaccine	Anaphylactic Shock	10
COVID-19 Vaccine	Anaphylactic Shock / Face Swelling / Angioedema	1
COVID-19 Vaccine	Anaphylaxis	22
COVID-19 Vaccine	Anaphylaxis / Vasovagal Syncope / AIDP / AMAN	1
COVID-19 Vaccine	Anemia / Heart Problems / Respiratory Problems / Weakness	1
COVID-19 Vaccine	Anxiety / Lack of Sleep / Agitation	1
COVID-19 Vaccine	Anxiety / Ongoing Confusion	1
COVID-19 Vaccine	Anxiety / Rapid Heartbeat / Depression / Chest Pain /	1

	Headache	
COVID-19 Vaccine	Anxiety / Shortness of Breath / Heart Palpitations	1
COVID-19 Vaccine	Appendicitis	6
COVID-19 Vaccine	Arm and Facial Paralysis / Difficulty Breathing	1
COVID-19 Vaccine	Arm and Hand Numbness / Pain	1
COVID-19 Vaccine	Arm and Leg Tingling / Heartburn / Headache	1
COVID-19 Vaccine	Arm and Neck Injury	1
COVID-19 Vaccine	Arm and Shoulder Injury	6
COVID-19 Vaccine	Arm Injury	15
COVID-19 Vaccine	Arm Injury / Fever	1
COVID-19 Vaccine	Arm Injury / Rotator Cuff Tear	1
COVID-19 Vaccine	Arm Leg and Breast Pain / Swollen Lymph Nodes	1
COVID-19 Vaccine	Arm Numbness / Tingling	1
COVID-19 Vaccine	Arm Numbness and Pain	1
COVID-19 Vaccine	Arm Pain	3
COVID-19 Vaccine	Arm Pain and Numbness / Swollen Lymph Nodes / Loss of Sleep	1
COVID-19 Vaccine	Arm Pit and Chest Swelling	1
COVID-19 Vaccine	Arm Pit and Chest Swelling	1
COVID-19 Vaccine	Arm Pit Swelling	1
COVID-19 Vaccine	Arrhythmia / Stroke / Tachycardia	1
COVID-19 Vaccine	Arrhythmia / Tachycardia	1
COVID-19 Vaccine	Aseptic Meningitis	1
COVID-19 Vaccine	Asthma	1
COVID-19 Vaccine	Asthma Attack / Fatigue	1
COVID-19 Vaccine	Atrial Fibrillation	4
COVID-19 Vaccine	Atrial Flutter	1
COVID-19 Vaccine	Autoimmune Disease	1
COVID-19 Vaccine	AV Block	1

COVID-19 Vaccine	Back Pain / Swollen Lymph Nodes	1
COVID-19 Vaccine	Back Pain and Lumps	1
COVID-19 Vaccine	Bacterial Pneumonia	1
COVID-19 Vaccine	Bell's Palsy	20
COVID-19 Vaccine	Bell's Palsy / Neuropathy	2
COVID-19 Vaccine	Bleeding Ulcers	1
COVID-19 Vaccine	Blood Clot / Brain Bleed	1
COVID-19 Vaccine	Blood Clot / Fluid in Heart and Lungs	1
COVID-19 Vaccine	Blood Clot / Stroke	1
COVID-19 Vaccine	Blood Clots	37
COVID-19 Vaccine	Blood Clots / Collapsed Lung	1
COVID-19 Vaccine	Blood Clots / Heart Murmur	1
COVID-19 Vaccine	Blood Clots / Leg Cramps / Dizziness	1
COVID-19 Vaccine	Blood Clots / Mucus	1
COVID-19 Vaccine	Blood Clots / Nose Bleed	1
COVID-19 Vaccine	Blood Clots / OVA	1
COVID-19 Vaccine	Blood Pressure / Chest Pain / Shortness of Breath	1
COVID-19 Vaccine	Blood Pressure Drop / Low Heart Rate / Vomiting / Fainting / Dizziness	1
COVID-19 Vaccine	Blood Vessel Break in Brain	1
COVID-19 Vaccine	Blurred Vision / Hives / Itching / Tremors	1
COVID-19 Vaccine	Body Aches	1
COVID-19 Vaccine	Bone Pain / Nausea / Trouble Thinking	1
COVID-19 Vaccine	Bowel Obstruction / Swollen Lymph Nodes	1
COVID-19 Vaccine	Brachial Neuritis	2
COVID-19 Vaccine	Brachial Plexopathy	1
COVID-19 Vaccine	Brain Aneurysm	1
COVID-19 Vaccine	Brain Bleed	1

COVID-19 Vaccine	Brain Bleeding / Blood Clots / Pneumonia	1
COVID-19 Vaccine	Brain Hemorrhage	1
COVID-19 Vaccine	Brain Inflammation / Encephalitis	1
COVID-19 Vaccine	Breakdown of Vital Organs	1
COVID-19 Vaccine	Broken Ankle / Concussion	1
COVID-19 Vaccine	Burning Mouth	1
COVID-19 Vaccine	Bursitis	5
COVID-19 Vaccine	Bursitis / Synovitis / Rotator Cuff Tear	1
COVID-19 Vaccine	Bursting Blood Vessels / Constricted Arteries	1
COVID-19 Vaccine	Cardiac Arrhythmia	1
COVID-19 Vaccine	Cardiac Atrial fibrillation	1
COVID-19 Vaccine	Cardiac Issues / Fatigue / Systemic Lupus Erythematosus	1
COVID-19 Vaccine	Cardiogenic Shock / Pericardial Effusion / Atrial Fibrillation	1
COVID-19 Vaccine	Cardiomyopathy	1
COVID-19 Vaccine	Cellulitis	2
COVID-19 Vaccine	Central and Peripheral Demyelinating Syndrome	1
COVID-19 Vaccine	Central Retinal Artery Occlusion	1
COVID-19 Vaccine	Central Retinal Vein Occlusion	1
COVID-19 Vaccine	Central Venous Sinus Thrombosis	3
COVID-19 Vaccine	Central Venus Thrombocytopenia	1
COVID-19 Vaccine	Cephalic Vein Clot	1
COVID-19 Vaccine	Chest Pain / Chest Cavity Inflammation Around Heart	1
COVID-19 Vaccine	Chest Pain / Fever / Headache / Chills	1
COVID-19 Vaccine	Chest Pain / Headache	1

COVID-19 Vaccine	Chest Pain / Joint Pain / Swelling	1
COVID-19 Vaccine	Chest Pain / Low Oxygen / Pneumonia	1
COVID-19 Vaccine	Chest Pain / Rapid Heartbeat	1
COVID-19 Vaccine	Chest Pain / Shortness of Breath	1
COVID-19 Vaccine	Chest Pains	2
COVID-19 Vaccine	Chest Pains / Fever / Chills / Sore Knees / Insomnia / Loss of Appetite	1
COVID-19 Vaccine	Chest Pressure / Rapid Heart Beat	1
COVID-19 Vaccine	Chest Tightness / Shortness of Breath	1
COVID-19 Vaccine	Chest-Neck Pain / Sweating / Blurred Vision / Spike Blood Pressure	1
COVID-19 Vaccine	Chills / Body Ache / Headache	1
COVID-19 Vaccine	Chills / Shaking / Inability to Breathe and Walk	1
COVID-19 Vaccine	Chronic Cough / Headache / Chest Tightness / Chest and Throat Pain	1
COVID-19 Vaccine	Chronic ITP	1
COVID-19 Vaccine	Chronic Lymphocytic Leukemia	1
COVID-19 Vaccine	CIDP	1
COVID-19 Vaccine	Cognitive Loss / Inflammation in Legs / Irregular Heart Rate	1
COVID-19 Vaccine	Cold Sweats / Sore Muscles / Headaches	1
COVID-19 Vaccine	Colitis / Crohn’s	1
COVID-19 Vaccine	Coma	1
COVID-19 Vaccine	Concussion	1
COVID-19 Vaccine	Concussion / Fainting	1
COVID-19 Vaccine	Concussion / Seizures / Chipped Teeth / Head and Neck Pain	1

COVID-19 Vaccine	Congestive Heart Failure / Enlarged Heart / Heart Palpitations	1
COVID-19 Vaccine	Constant Diarrhea	1
COVID-19 Vaccine	Constant Pain and Numbness in Fingers and Arm	1
COVID-19 Vaccine	Constipation / Indigestion / Abdominal Pain / Fatigue / Dizziness / Headache / Nausea / Vomiting / Chest Pains	1
COVID-19 Vaccine	Cord Compression Myelopathy	1
COVID-19 Vaccine	Cornea Transplant	1
COVID-19 Vaccine	Cough / Cold symptoms	1
COVID-19 Vaccine	Coughing Blood / Severe Chest Pain / Severe Burning Sensation / Blood Clots / Difficulty Breathing	1
COVID-19 Vaccine	COVID Arm / Extreme Fatigue / Joint and Muscle Pain / High Blood Pressure / Heart Irregularities	1
COVID-19 Vaccine	COVID Pneumonia	2
COVID-19 Vaccine	Creutzfeldt-Jacobs	1
COVID-19 Vaccine	Deafness	1
COVID-19 Vaccine	Deafness (Right Side)	1
COVID-19 Vaccine	Death	53
COVID-19 Vaccine	Death / Guillain-Barré Syndrome (GBS)	2
COVID-19 Vaccine	Death / Thrombocytopenia	1
COVID-19 Vaccine	Decreased Heart Rate / Low Blood Pressure	1
COVID-19 Vaccine	Deep Vein Thrombosis (DVT)	9
COVID-19 Vaccine	Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE)	4
COVID-19 Vaccine	Dermatomyositis	1
COVID-19 Vaccine	Difficulty Breathing	3
COVID-19 Vaccine	Difficulty Breathing / Coughing Blood / Swollen	1

	Legs	
COVID-19 Vaccine	Difficulty Breathing / Migraine / Chills / Muscle Pain	1
COVID-19 Vaccine	Difficulty Breathing / Muscle Tension	1
COVID-19 Vaccine	Difficulty Breathing / Nausea / Dizziness / Weakness / Loss of Appetite / Rash / Pain	1
COVID-19 Vaccine	Difficulty Breathing / Nausea / Paralysis / Dizziness	1
COVID-19 Vaccine	Difficulty Breathing / Numbness	1
COVID-19 Vaccine	Difficulty Breathing / Pneumonia / Body Aches / Headaches / Blurred Vision / Dizziness / Weakness	1
COVID-19 Vaccine	Difficulty Breathing and Speaking / Disorientation / Muscle Weakness	1
COVID-19 Vaccine	Disoriented / Unresponsive	1
COVID-19 Vaccine	Diverticulitis	1
COVID-19 Vaccine	Dizziness	1
COVID-19 Vaccine	Dizziness / Broken Leg & Ankle	1
COVID-19 Vaccine	Dizziness / Difficulty Breathing / Foggy Thinking / Dehydration / Numbness / Faintness	1
COVID-19 Vaccine	Dizziness / Head Body Injury	1
COVID-19 Vaccine	Dizziness / Headache / Lethargic / Pressure in Head and Brain	1
COVID-19 Vaccine	Dizziness / Headaches / Facial Paralysis	1
COVID-19 Vaccine	Dizziness / Headaches / Loss of Balance	1
COVID-19 Vaccine	Dizziness / Lightheadedness	1
COVID-19 Vaccine	Dizziness / Loss of Sensation	1

COVID-19 Vaccine	Dizziness / Numbness / Rash	1
COVID-19 Vaccine	Dizziness / Shortness of Breath / Burning Sensation	1
COVID-19 Vaccine	Dizziness / Tachycardia / High Blood Pressure	1
COVID-19 Vaccine	Dizziness / Vomiting / High Blood Pressure	1
COVID-19 Vaccine	Dizziness / Skull Fracture / Concussion	1
COVID-19 Vaccine	DVT / Serum Reaction / Paresthesia / Calculus of Kidney / Gross Hematuria	1
COVID-19 Vaccine	Ear Popping / Confusion / Incoherent / Hard to Concentrate and Focus	1
COVID-19 Vaccine	Elevated Blood Pressure	2
COVID-19 Vaccine	Elevated Blood Pressure / Tremors / Dizziness	1
COVID-19 Vaccine	Elevated Blood Pressure and Heart Rate	2
COVID-19 Vaccine	Elevated Heart Rate / Fever	1
COVID-19 Vaccine	Elevated Heart Rate / Low Blood Pressure	1
COVID-19 Vaccine	Elevated Troponin	1
COVID-19 Vaccine	Elevated Troponin / Decreased Platelet Levels	1
COVID-19 Vaccine	Emotional Distress / Psychiatric Breakdown	1
COVID-19 Vaccine	Encephalopathy	1
COVID-19 Vaccine	Enlarged Lymph Nodes	1
COVID-19 Vaccine	Enlarged Lymph Nodes / Fainted / Dizziness / Nausea / Fatigue / Muscle Aches	1
COVID-19 Vaccine	Eosinophil / Hypoalbuminemia / Thrombocytosis	1
COVID-19 Vaccine	Eosinophilia / Systemic Inflammation	1
COVID-19 Vaccine	Erythema	1
COVID-19 Vaccine	Erythema Nodosum	1

COVID-19 Vaccine	Exacerbation of Pre-Existing Condition	1
COVID-19 Vaccine	Extreme Arm and Leg Pain	1
COVID-19 Vaccine	Extreme Dizziness / Fatigue / Broken Back	1
COVID-19 Vaccine	Extreme Fatigue / Brain Fog	1
COVID-19 Vaccine	Extreme Fatigue / Heart Irregularities	1
COVID-19 Vaccine	Extreme Fatigue / Heart Palpitation	1
COVID-19 Vaccine	Extreme Fatigue / Nausea / Dizziness / Nerve Pain / Abdominal Pain	1
COVID-19 Vaccine	Extreme Fatigue / Shortness of Breath / Elevated Blood Pressure / Left Ventricular Cardiomalogy	1
COVID-19 Vaccine	Extreme Fatigue / Swelling and Pain in Lower Extremities	1
COVID-19 Vaccine	Extreme Joint Pain and Swelling	1
COVID-19 Vaccine	Extreme Swelling	1
COVID-19 Vaccine	Eye Stroke	1
COVID-19 Vaccine	Face Spasms / Hypertension	1
COVID-19 Vaccine	Face Swelling / Inflammation / Leg Bruising / Numbness on Neck, Head, Face and Left Hand Fingers / Severe Kidney Pain / Breast Pain	1
COVID-19 Vaccine	Facial Droop / Tremors	1
COVID-19 Vaccine	Facial Numbness	1
COVID-19 Vaccine	Facial Numbness / Migraine	1
COVID-19 Vaccine	Facial Numbness / Tightness In Chest / High Heart Rate	1
COVID-19 Vaccine	Facial Paralysis	1
COVID-19 Vaccine	Facial Spasms	1
COVID-19 Vaccine	Facial Spasms and	1

	Paralysis	
COVID-19 Vaccine	Facial Swelling	1
COVID-19 Vaccine	Facial Swelling / Weakness / Dizziness / Vision Problems / Severe Hypertension	1
COVID-19 Vaccine	Facial Swelling and Burning / Skin Peeling / Fatigue	1
COVID-19 Vaccine	Fainted	13
COVID-19 Vaccine	Fainted / Allergic Reaction / Hives	1
COVID-19 Vaccine	Fainted / Blood Clots	1
COVID-19 Vaccine	Fainted / Broken Nose	1
COVID-19 Vaccine	Fainted / Broken Teeth	1
COVID-19 Vaccine	Fainted / Chills / Joint Pain / Rash	1
COVID-19 Vaccine	Fainted / Convulsions / Confusion / Throat Swelling	1
COVID-19 Vaccine	Fainted / Dizziness / Weakness	1
COVID-19 Vaccine	Fainted / Elbow Injury	1
COVID-19 Vaccine	Fainted / Headache / Chest Pain / Muscle Spasms / Shortness of Breathe / Weakness / Anxiety / High Blood Pressure	1
COVID-19 Vaccine	Fainted / Hematoma / Concussion	1
COVID-19 Vaccine	Fainted / Seizure	2
COVID-19 Vaccine	Fainted / Seizure / Lost Control of Bladder	1
COVID-19 Vaccine	Fainted / Subdural Hematoma	1
COVID-19 Vaccine	Fainted / Vomiting / Convulsions	1
COVID-19 Vaccine	Fainting	8
COVID-19 Vaccine	Fainting / Broken Ankle	1
COVID-19 Vaccine	Fainting / Chin Laceration	1
COVID-19 Vaccine	Fainting / Difficulty Breathing	1

COVID-19 Vaccine	Fainting / Fatigue / Dizziness / Nausea	1
COVID-19 Vaccine	Fainting / Head Injury	1
COVID-19 Vaccine	Fainting / High Blood Pressure / Low Blood Sugar / Severe Migraines	1
COVID-19 Vaccine	Fainting / Injury to Face	1
COVID-19 Vaccine	Fainting / Mouth Injury	1
COVID-19 Vaccine	Fainting / Vomiting / Convulsions	1
COVID-19 Vaccine	Fatigue / Back Pain / Chest Pain / Severe Headache	1
COVID-19 Vaccine	Fatigue / Body Ache / Headache / Uncontrollable Blood Pressure and Heart Rate	1
COVID-19 Vaccine	Fatigue / Brain Fog	1
COVID-19 Vaccine	Fatigue / Dizziness / Nausea / Diarrhea	1
COVID-19 Vaccine	Fatigue / Dizziness / Nausea / Hallucinations / Brain Fog	1
COVID-19 Vaccine	Fatigue / Dizziness / Severe Leg Pain	1
COVID-19 Vaccine	Fatigue / Fever / Malaise / Dehydration / Acute Kidney Injury / Loss of Appetite / Nausea	1
COVID-19 Vaccine	Fatigue / Heart Palpitations	1
COVID-19 Vaccine	Fatigue / Loss of Appetite / Confusion	1
COVID-19 Vaccine	Fatigue / Nausea / Abdominal Pain / Leg Weakness	1
COVID-19 Vaccine	Fatigue / Nausea / Headache / Fever / Body Ache / Sweating	1
COVID-19 Vaccine	Fatigue / Pain / Nausea / Headache	1
COVID-19 Vaccine	Fatigue / Rash / Pain	1
COVID-19 Vaccine	Fatigue / Sore Armpit / Headache / Elevated Heart Rate	1

COVID-19 Vaccine	Feeling Faint / Dizziness	1
COVID-19 Vaccine	Feeling Ill / Blood Pressure Spikes	1
COVID-19 Vaccine	Fever / Abdominal Pain	1
COVID-19 Vaccine	Fever / Aches	1
COVID-19 Vaccine	Fever / Arm Injury	1
COVID-19 Vaccine	Fever / Chest Pain	1
COVID-19 Vaccine	Fever / Chills / Headache / Arm Pain / weakness / Loss of Appetite	1
COVID-19 Vaccine	Fever / Chills / Nausea / Dizziness / Fatigue / Dark Stools	1
COVID-19 Vaccine	Fever / Chills / Severe Chest Pain / Shortness of Breath / Confusion	1
COVID-19 Vaccine	Fever / Chills / Shaking / Weakness	1
COVID-19 Vaccine	Fever / Chills / Shortness of Breath / Rash / Loss of Appetite / Dehydration	1
COVID-19 Vaccine	Fever / Congestion	2
COVID-19 Vaccine	Fever / Delusions / Organ Failure / Extreme Weight Loss / Inability to walk	1
COVID-19 Vaccine	Fever / Difficulty Walking	1
COVID-19 Vaccine	Fever / Headache / Body Pain / Vomiting	1
COVID-19 Vaccine	Fever / High Blood Pressure	1
COVID-19 Vaccine	Fever / Migraine / Vomiting	1
COVID-19 Vaccine	Fever / Nausea / Chills / Blood Clots Enlarged Lymph nodes	1
COVID-19 Vaccine	Fever / Nausea / Difficulty Breathing / Headache	1
COVID-19 Vaccine	Fever / Nausea / Fainted / Tiredness	1
COVID-19 Vaccine	Fever / Septic / Dehydration	1
COVID-19 Vaccine	Fever / Severe Bone and Joint Pain	1

COVID-19 Vaccine	Fever / Severe Head and Neck Pain / Body Aches / Heart Palpitations	1
COVID-19 Vaccine	Fever / Shaking / Broken Teeth	1
COVID-19 Vaccine	Fever / Swelling / Vomiting / Tonsil Edema / Dehydration / Heart Irregularities / Muscle Fatigue / Fatigue	1
COVID-19 Vaccine	Fever / Vomiting / Body Aches	1
COVID-19 Vaccine	Fever / Vomiting / Dehydration	1
COVID-19 Vaccine	Fried Shoulder and Leg Muscles / Swollen Hands / Ankle Pain	1
COVID-19 Vaccine	Flare Up of Rheumatoid Arthritis	1
COVID-19 Vaccine	Flu Like Symptoms / Dehydration	1
COVID-19 Vaccine	Frozen Shoulder	3
COVID-19 Vaccine	Frozen Shoulder / Tendinosis	1
COVID-19 Vaccine	Gastritis	1
COVID-19 Vaccine	Grand Mal Seizure	2
COVID-19 Vaccine	Guillain-Barré Syndrome (GBS)	30
COVID-19 Vaccine	Guillain-Barré Syndrome (GBS) / Death	1
COVID-19 Vaccine	Hand and Arm Numbness / Knots Under Skin / Joint Pain	1
COVID-19 Vaccine	Hand and Arm Numbness and Tingling / Rapid Heartbeat	1
COVID-19 Vaccine	Head Injury	1
COVID-19 Vaccine	Headache	1
COVID-19 Vaccine	Headache / Bilateral Neuropathy / Skin Discoloration	1
COVID-19 Vaccine	Headache / Blindness	1
COVID-19 Vaccine	Headache / Blood Pressure Drop / Dizziness	1

COVID-19 Vaccine	Headache / Fatigue / Chest Pressure	1
COVID-19 Vaccine	Headache / Leg Swelling / Pain / Blood Clots / Rare Blood Disease / Pneumonia	1
COVID-19 Vaccine	Headache / Muscle Ache / Rash / Rapid Heartbeat / Fever	1
COVID-19 Vaccine	Headache / Nausea / Diarrhea	1
COVID-19 Vaccine	Headache / Vomiting / Ketoacidosis	1
COVID-19 Vaccine	Headache / Weakness / Tinnitus	1
COVID-19 Vaccine	Headaches / Body Aches / Blood Clots	1
COVID-19 Vaccine	Headaches / Dizziness	1
COVID-19 Vaccine	Headaches / Extreme Leg Weakness	1
COVID-19 Vaccine	Headaches / Fatigue	1
COVID-19 Vaccine	Headaches / Muscle Cramps	1
COVID-19 Vaccine	Headaches / Rash	1
COVID-19 Vaccine	Headaches / Rashes / High Blood Pressure	1
COVID-19 Vaccine	Headaches / Tinnitus / Extreme Fatigue	1
COVID-19 Vaccine	Headaches / Tinnitus / Lightheadedness / Blurred Vision / Dizziness / Weakness	1
COVID-19 Vaccine	Hearing Loss	13
COVID-19 Vaccine	Hearing Loss / High Blood Pressure	1
COVID-19 Vaccine	Hearing Loss / Vocal Cord Paralysis / Fatigue / Neck Pain / Numbness / Head Pressure	1
COVID-19 Vaccine	Heart Attack	6
COVID-19 Vaccine	Heart Attack / Death	1
COVID-19 Vaccine	Heart Failure	1
COVID-19 Vaccine	Heart Failure / Atrial	1

	Fibrillation	
COVID-19 Vaccine	Heart Failure / Renal Failure	1
COVID-19 Vaccine	Heart Fibrillation	1
COVID-19 Vaccine	Heart Inflammation	1
COVID-19 Vaccine	Heart Issues / Stroke	1
COVID-19 Vaccine	Heart Palpitations	3
COVID-19 Vaccine	Heart Palpitations / Heartburn / Buzzing / Chest Pain	1
COVID-19 Vaccine	Heart Palpitations / Light Headedness	1
COVID-19 Vaccine	Heart Palpitations / Shaking / Shortness of Breath	1
COVID-19 Vaccine	Heart Racing / Palpitations / Fluttering	1
COVID-19 Vaccine	Heavy Vaginal Bleeding	1
COVID-19 Vaccine	Hemorrhagic Stroke	1
COVID-19 Vaccine	Herpes Zoster / Supraclavicular Lymphadenopathy	1
COVID-19 Vaccine	Herpes Zoster / Transverse Myelitis	1
COVID-19 Vaccine	Hidradenitis Suppurativa	1
COVID-19 Vaccine	High Blood pressure	3
COVID-19 Vaccine	High Blood Pressure / Chest Tightness / Headaches / Inability to Focus	1
COVID-19 Vaccine	High Blood Pressure / Chronic Headaches / Vertigo / Chest Pains / Ear Pain and Pressure / Eye pain / Changes in Vision	1
COVID-19 Vaccine	High Blood Pressure / Dizziness / Difficulty Breathing	1
COVID-19 Vaccine	High Blood Pressure / Facial Swelling and Numbness	1
COVID-19 Vaccine	High Blood Pressure / Fever / Seizure / Short	1

	Term Memory Loss / Numbness and Aches	
COVID-19 Vaccine	High Blood Pressure / Pain Neck, Chest, Back and Arm	1
COVID-19 Vaccine	High Blood Pressure / Severe Dizziness	1
COVID-19 Vaccine	High Blood Pressure / Tachycardia / Shortness of Breathe / Severe Headache	1
COVID-19 Vaccine	High Heart Rate / Brain Fog / Chronic Fatigue	1
COVID-19 Vaccine	High Pitched Sound in Ears / Insomnia	1
COVID-19 Vaccine	Hives	2
COVID-19 Vaccine	Hives / Difficulty Breathing	1
COVID-19 Vaccine	Hives / Fatigue / Headache / Tremors / Weakness	1
COVID-19 Vaccine	Hives / Fatigue / Vomiting / Tremors	1
COVID-19 Vaccine	Hives / Headache Swelling / Dizziness	1
COVID-19 Vaccine	Hives / Skin Discoloration	1
COVID-19 Vaccine	Hives / Urticaria / Angioedema	1
COVID-19 Vaccine	Hypertension	1
COVID-19 Vaccine	Hypertension / Tachycardia	1
COVID-19 Vaccine	Hypoglossal Nerve Palsy	1
COVID-19 Vaccine	Hypotension	1
COVID-19 Vaccine	Idiopathic Intracranial Hypertension / Esotropia	1
COVID-19 Vaccine	Idiopathic/Immune Thrombocytopenia Purpura (ITP)	8
COVID-19 Vaccine	Inability to Stand / Walk / Do Daily Routines	1
COVID-19 Vaccine	Increased Heart Rate / Convulsions / Severe Headache / Unable to Walk or Stand / Light Sensitivity	1
COVID-19 Vaccine	Infectious Cellulitis	1
COVID-19 Vaccine	Inflamed Lymph Nodes	1

COVID-19 Vaccine	Inflamed Rotator Cuff	1
COVID-19 Vaccine	Inflammation / High Blood Pressure and Heart Rate / Rash / Hives / Trouble Breathing	1
COVID-19 Vaccine	Inflammation / Swelling / Extreme Pain	1
COVID-19 Vaccine	Inflammation in Hands and Wrists	1
COVID-19 Vaccine	Inflammatory Arthritis	1
COVID-19 Vaccine	Inflammatory Myelitis	1
COVID-19 Vaccine	Insomnia	1
COVID-19 Vaccine	Intense Chest Pains	1
COVID-19 Vaccine	Internal Bleeding / Mouth Blisters	1
COVID-19 Vaccine	Interstitial Lung Disease / Chronic Respiratory Failure	1
COVID-19 Vaccine	Irregular Heart Beat / Heart Failure	1
COVID-19 Vaccine	Irregular Heart Rhythm / Tachycardia / Severe Chest Pain / Left Side Numbness	1
COVID-19 Vaccine	Ischemic Colitis	2
COVID-19 Vaccine	Ischemic Stroke	3
COVID-19 Vaccine	Itching / Rash / Nausea / Vomiting	1
COVID-19 Vaccine	ITP / Chronic Bleeding Disorder	1
COVID-19 Vaccine	Jaundice / Lethargy / Loss of Appetite	1
COVID-19 Vaccine	Jaw, Chest and Neck Pain / Chest Pressure / Shortness of Breath / Extreme Nausea	1
COVID-19 Vaccine	Joint Inflammation	1
COVID-19 Vaccine	Joint Inflammation / Joint Pain	1
COVID-19 Vaccine	Joint Pain and Swelling	1
COVID-19 Vaccine	Kidney Injury / Arm Injury	1
COVID-19 Vaccine	Kidney Stones	1
COVID-19 Vaccine	Left / Right Leg Numbness	1

COVID-19 Vaccine	Left Arm and Hand Numbness	1
COVID-19 Vaccine	Left Perilymphatic Fistula / Right Perilymphatic Fistula / Elevated Intracranial Pressure / Bilateral Eustachian Tube Dysfunction	1
COVID-19 Vaccine	Left Side Numbness / Back Pain / Ear Pain / Drooling / Brain Fog	1
COVID-19 Vaccine	Left Side Numbness / Fainted	1
COVID-19 Vaccine	Left Side Numbness / Knee and Leg Pain	1
COVID-19 Vaccine	Left Side Paralysis	1
COVID-19 Vaccine	Left Side Weakness	1
COVID-19 Vaccine	Left Side Weakness / Difficulty Breathing / Migraine / Heart Palpitations / Wheezing / Dizziness / Joint Pain	1
COVID-19 Vaccine	Leg Pain	1
COVID-19 Vaccine	Leg Pain / Chest Pain	1
COVID-19 Vaccine	Lesions	1
COVID-19 Vaccine	Leukoycto Clastic Vasculitis with Dermal Neutrophil	1
COVID-19 Vaccine	Lichen Planus	1
COVID-19 Vaccine	Light Headedness / Extreme Fatigue / Faintness	1
COVID-19 Vaccine	Lightheaded / Cold Sweat / Chills	1
COVID-19 Vaccine	Lightheaded / Dizziness / Nausea	1
COVID-19 Vaccine	Lightheaded / Throat Swelling / Difficulty Breathing	1
COVID-19 Vaccine	Lipoma of Subcutaneous Tissue (Left Arm)	1
COVID-19 Vaccine	Liver Damage	1
COVID-19 Vaccine	Liver Injury	1
COVID-19 Vaccine	LLE / LUE Weakness / Facial Numbness /	1

	Difficulty Speaking	
COVID-19 Vaccine	Loss of Body Functions	1
COVID-19 Vaccine	Loss of Eye Sight	1
COVID-19 Vaccine	Loss of Sensation in Extremities / Tinnitus / Headache	1
COVID-19 Vaccine	Lost Consciousness	1
COVID-19 Vaccine	Low Blood Pressure / Chest Pain	1
COVID-19 Vaccine	Low Blood Pressure / Difficulty Breathing	1
COVID-19 Vaccine	Low Blood Pressure / Fluid In Lungs / Pancreatitis	1
COVID-19 Vaccine	Low Blood Sugar / Low Blood Pressure / Low Energy / Pneumonia	1
COVID-19 Vaccine	Low Hemoglobin	1
COVID-19 Vaccine	Low O2 Saturation	1
COVID-19 Vaccine	Low Oxygen / Fatigue	1
COVID-19 Vaccine	Low Platelet Count	1
COVID-19 Vaccine	Lung Infection	1
COVID-19 Vaccine	Lung Nodules / Migraine	1
COVID-19 Vaccine	Lymph Node Mass	1
COVID-19 Vaccine	Memory Loss / Hallucinating	1
COVID-19 Vaccine	Meningitis / Syringomyelia	1
COVID-19 Vaccine	Mesenteric Venous Thrombosis	1
COVID-19 Vaccine	Migraine / Chronic Fatigue	1
COVID-19 Vaccine	Mesenteric Venous Thrombosis / Septic Thrombophlebitis	1
COVID-19 Vaccine	Migraine / Joint Pain / Fatigue	1
COVID-19 Vaccine	Migraine Headache	2
COVID-19 Vaccine	Migraine Headaches / High Blood Pressure	1
COVID-19 Vaccine	Mild Heart Attack	1
COVID-19 Vaccine	Miscarriage	1

COVID-19 Vaccine	Multisystem Inflammatory Syndrome	1
COVID-19 Vaccine	Muscle Aches / Swelling / Cough / Chills / Night Sweats / Dizziness / Elevated WBC / Stomach Ache / Fatigue / Difficulty Ambulating	1
COVID-19 Vaccine	Muscle Pain / Body Aches	1
COVID-19 Vaccine	Muscle Spasms / Breathing Abnormality / Pain	1
COVID-19 Vaccine	Myasthenia Gravis Disease	2
COVID-19 Vaccine	Myocarditis	19
COVID-19 Vaccine	Myocarditis / Heart Attack	1
COVID-19 Vaccine	Myocarditis / Pericarditis	5
COVID-19 Vaccine	Myocarditis / Pneumonia	1
COVID-19 Vaccine	Myoclonus Seizures / Uncontrollable Laughter / Fatigue / Headaches / Loss of Taste, Appetite, Weight / High Blood Pressure / Tinnitus / Ingrown Nails / Blurry Vision / Constipation / Dehydration / Confusion / Numbness	1
COVID-19 Vaccine	Myopericarditis	5
COVID-19 Vaccine	Nausea / Chest Pains / Migraines / Numbness	1
COVID-19 Vaccine	Nausea / Diarrhea / Headache / Sweating	1
COVID-19 Vaccine	Nausea / Dizziness / Difficulty Breathing / Fever / Sweating	1
COVID-19 Vaccine	Nausea / Facial Pain / Trouble Thinking / Pain in Shoulders and Knees / Heart Fluttering	1
COVID-19 Vaccine	Nausea / Fatigue / Tongue Swelling / Neck and Shoulder Pain	1
COVID-19 Vaccine	Nausea / Fever / Shortness of Breath	1
COVID-19 Vaccine	Nausea / Hives / Shaking	1
COVID-19 Vaccine	Nausea / Right Limb Weakness / Vomiting / Memory Loss / Confusion	1

COVID-19 Vaccine	Nausea / Vomiting / Diarrhea / Leg and Knee Pain / Encephalopathy	1
COVID-19 Vaccine	Nausea / Vomiting / Diarrhea / Loss of Appetite / Weight Loss / Malnutrition	1
COVID-19 Vaccine	Nausea / Vomiting / Headache / Difficulty Breathing	1
COVID-19 Vaccine	Nausea / Vomiting / Lethargy	1
COVID-19 Vaccine	Nerve Damage	1
COVID-19 Vaccine	Nerve Damage / Muscle Atrophy	1
COVID-19 Vaccine	Nerve Pain / Vision Weakness / Muscle Fatigue / Headache	1
COVID-19 Vaccine	Neurologic / Cardiovascular / Gynecologic Issues	1
COVID-19 Vaccine	Neurologic Disorder	1
COVID-19 Vaccine	Neurologic Symptoms	2
COVID-19 Vaccine	Neurological Damage	1
COVID-19 Vaccine	Neurological Reaction / Paresthesia	1
COVID-19 Vaccine	Neuropathy / Joint Pain / Palpitations	1
COVID-19 Vaccine	Night Sweats / Fatigue / Nausea / Vomiting / Diarrhea	1
COVID-19 Vaccine	Non-specific Paresthesia	1
COVID-19 Vaccine	Not Specified	58
COVID-19 Vaccine	Numbness	2
COVID-19 Vaccine	Numbness / Bruising / Pain	1
COVID-19 Vaccine	Numbness / Pain / Tingling / Inability to Stand or Walk	1
COVID-19 Vaccine	Numbness / Swelling / Chest Pain	1
COVID-19 Vaccine	Numbness / Weakness in Legs	1
COVID-19 Vaccine	Numbness and Bruising	1

COVID-19 Vaccine	Numbness in Feet	1
COVID-19 Vaccine	Numbness on Entire Left Side	1
COVID-19 Vaccine	Open Wound / Hand & Foot / COVID Pneumonia / Enlarged Lymph Nodes	1
COVID-19 Vaccine	Optic Migraine	1
COVID-19 Vaccine	Pain / Headache / Facial Distortion	1
COVID-19 Vaccine	Pain / Mouth Infection	1
COVID-19 Vaccine	Pain / Nausea / Dizziness / Fainting	1
COVID-19 Vaccine	Pain / Numbness / Weakness in Arm	1
COVID-19 Vaccine	Pain / Skin Lesions	1
COVID-19 Vaccine	Pain in Shins and Ankles	1
COVID-19 Vaccine	Pain Throughout Body	1
COVID-19 Vaccine	Pancolitis / C. Diff. Infection	1
COVID-19 Vaccine	Pancreatitis	1
COVID-19 Vaccine	Pancytopenia	1
COVID-19 Vaccine	Paralysis	6
COVID-19 Vaccine	Paralysis / Pain / Headaches	1
COVID-19 Vaccine	Paralyzed Vocal Cord	1
COVID-19 Vaccine	Paresthesia	3
COVID-19 Vaccine	Paresthesia / Nerve Pain / Muscle and Joint Pain / Weakness / Tongue Tingling / Eye Irritation	1
COVID-19 Vaccine	Parsonage Turner Syndrome (PTS)	3
COVID-19 Vaccine	Passed Out	1
COVID-19 Vaccine	Pericardial Enhancement	1
COVID-19 Vaccine	Pericarditis	17
COVID-19 Vaccine	Pericardium Cyst	1
COVID-19 Vaccine	Peripheral Neuropathy	1
COVID-19 Vaccine	Petchiae / Low Platelets / Splenectomy	1

COVID-19 Vaccine	Petechiae	1
COVID-19 Vaccine	Petechiae / Bleeding	1
COVID-19 Vaccine	Petechiae / Headache / Nausea	1
COVID-19 Vaccine	Phantosmia	1
COVID-19 Vaccine	Pneumonia	1
COVID-19 Vaccine	Pneumonia / Bronchitis	1
COVID-19 Vaccine	Pneumonia / Decreased Potassium	1
COVID-19 Vaccine	Poisoning by Vaccine and Biological Substances	1
COVID-19 Vaccine	Polymyalgia Rheumatica	1
COVID-19 Vaccine	Polymyositis	1
COVID-19 Vaccine	Polyneuropathy / Critical Illness Myopathy	1
COVID-19 Vaccine	Post Stroke Recudence	1
COVID-19 Vaccine	Posterior Leukoencephalopathy	1
COVID-19 Vaccine	Postural Orthostatic Tachycardia Syndrome (POTS)	2
COVID-19 Vaccine	Pressure in Head and Neck / Chest Pain / Blood Clots	1
COVID-19 Vaccine	Primary Sclerosing Cholangitis	1
COVID-19 Vaccine	Psoriasis / Moderate Osteoarthritis	1
COVID-19 Vaccine	Psoriasis / Onycholysis / Edema / Xerosis	1
COVID-19 Vaccine	Psychosis	1
COVID-19 Vaccine	Ptosis / Palsy	2
COVID-19 Vaccine	Pulmonary Embolism	19
COVID-19 Vaccine	Pulmonary Embolism / Blood Clots / Heart Strain	1
COVID-19 Vaccine	Pulmonary Embolism / Hypothyroidism / Generalized Joint Pain	1
COVID-19 Vaccine	Pulmonary Embolism / Lung Infarction / Hypercoagulability	1

COVID-19 Vaccine	Queasy Feeling	1
COVID-19 Vaccine	Quincke Edema / Injection Site Injury / Fever / Swelling	1
COVID-19 Vaccine	Radial Artery Thrombus / Angina	1
COVID-19 Vaccine	Rapid Heart Rate	1
COVID-19 Vaccine	Rapid Heart Rate / Difficulty Breathing	1
COVID-19 Vaccine	Rapid Heartbeat	4
COVID-19 Vaccine	Rash	15
COVID-19 Vaccine	Rash / Allergic Reaction	1
COVID-19 Vaccine	Rash / Elevated Heart Rate / Chest Pain / Dizziness	1
COVID-19 Vaccine	Rash / Hives	1
COVID-19 Vaccine	Rash / Nerve Pain	1
COVID-19 Vaccine	Rash / Shortness of Breath / Rapid Heartbeat / Dizziness / Fainted / Joint Pain / Headache	1
COVID-19 Vaccine	Rash / Swelling	2
COVID-19 Vaccine	Rashes	1
COVID-19 Vaccine	Recurring Epistaxis	1
COVID-19 Vaccine	Respiratory Failure / Influenza A / Necrotizing Pneumonia / Acute Kidney Injury	1
COVID-19 Vaccine	Rhabdomyolysis / Dizziness / Chest Pain / Right Bundled Branch Block	1
COVID-19 Vaccine	Rheumatoid Arthritis	1
COVID-19 Vaccine	Right Dural Venus Thrombosis	1
COVID-19 Vaccine	Right Side Numbness / Loss of Voice / Bowel Movement Issues	1
COVID-19 Vaccine	Right Side Numbness / Nausea / Dizziness	1
COVID-19 Vaccine	Right Side Paralysis	1
COVID-19 Vaccine	Robust Reactions	1

COVID-19 Vaccine	Rotator Cuff Tear	1
COVID-19 Vaccine	Rotator Cuff Tear / Advanced Tendinopathy / Left Shoulder Capsulitis	1
COVID-19 Vaccine	Ruptured Tendon	1
COVID-19 Vaccine	Seizure / Dysphagia	1
COVID-19 Vaccine	Seizures	11
COVID-19 Vaccine	Sepsis	1
COVID-19 Vaccine	Severe Abdominal Pain	1
COVID-19 Vaccine	Severe Allergic Reaction	14
COVID-19 Vaccine	Severe Anaphylaxis	1
COVID-19 Vaccine	Severe Aplastic Anemia	1
COVID-19 Vaccine	Severe Arm Pain	1
COVID-19 Vaccine	Severe Arm Pain / Fainting	1
COVID-19 Vaccine	Severe Arm Pain / Rapid Heartbeat	1
COVID-19 Vaccine	Severe Back, Neck and Head Pain	1
COVID-19 Vaccine	Severe Bruising / Arm Pain	1
COVID-19 Vaccine	Severe Chest and Abdominal Pain	1
COVID-19 Vaccine	Severe Chest and Head Pain	1
COVID-19 Vaccine	Severe Chest Pain	1
COVID-19 Vaccine	Severe Chest Pain / Shortness of Breath / Migraine like Pain / Seizure / Dizziness / Light Sensitivity / Dry Mouth / Hoarse Throat / Tingling / Numbness	1
COVID-19 Vaccine	Severe Chills / Pain / Fever / Vomiting / Fainted	1
COVID-19 Vaccine	Severe Chronic Pain	1
COVID-19 Vaccine	Severe Fatigue / Fever / Chills / Pain	1
COVID-19 Vaccine	Severe Flu Like Symptoms	1
COVID-19 Vaccine	Severe Groin, Knee, Elbow and Hand Pain	1
COVID-19 Vaccine	Severe Headache / Body	1

	Aches / Difficulty Concentrating / Photo Sensitivity	
COVID-19 Vaccine	Severe Headache / Chills / Nausea / Vomiting / Fatigue	1
COVID-19 Vaccine	Severe Headache / Elevated Blood Pressure and Pulse / Abdominal Pain	1
COVID-19 Vaccine	Severe Headaches / Tingling / Numbness	1
COVID-19 Vaccine	Severe Itching / Allergic Reaction	1
COVID-19 Vaccine	Severe Itching / Blisters	1
COVID-19 Vaccine	Severe Joint Pain / Fever / Asthma	1
COVID-19 Vaccine	Severe Leg and Back Pain / Extreme Fatigue	1
COVID-19 Vaccine	Severe Leg Pain	1
COVID-19 Vaccine	Severe Lower Back Pain / Dizziness / Headaches	1
COVID-19 Vaccine	Severe Migraines / Pain / Fatigue	1
COVID-19 Vaccine	Severe Muscle Pain / Internal Bleeding	1
COVID-19 Vaccine	Severe Nausea / Dizziness / Dehydration	1
COVID-19 Vaccine	Severe Pain and Fatigue	1
COVID-19 Vaccine	Severe Pain and Weakness in Shoulder and Arm	1
COVID-19 Vaccine	Severe Rash / Hives	1
COVID-19 Vaccine	Severe Rashes	1
COVID-19 Vaccine	Severe Reaction / Low Heart Rate	1
COVID-19 Vaccine	Severe Tinnitus / Dizziness	1
COVID-19 Vaccine	Severe Vaginal Bleeding	1
COVID-19 Vaccine	Severe Vasculitis	1
COVID-19 Vaccine	Severe Vertigo / Leg Cramps / Exhaustion / Night Sweats / Headaches	1
COVID-19 Vaccine	Shaking / Muscle	1

	Weakness / Nerve Pain / GBS like symptoms	
COVID-19 Vaccine	Shaking / Numbness / Swelling / Severe Chest Pressure and Pressure / Sweating	1
COVID-19 Vaccine	Shaking / Swelling / Headaches	1
COVID-19 Vaccine	Shingles	6
COVID-19 Vaccine	Shingles / COVID-19	1
COVID-19 Vaccine	Shocking Sensation in Arteries or Veins / Fatigue / Flu Like Symptoms / Pain in Stomach and Legs	1
COVID-19 Vaccine	Shortness of Breath / Arm Injury	1
COVID-19 Vaccine	Shortness of Breath / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Chest Pains / Extreme Swelling	1
COVID-19 Vaccine	Shortness of Breath / Chest Pressure / Tingling in Hands and Feet	1
COVID-19 Vaccine	Shortness of Breath / Confusion / Severe Headache	1
COVID-19 Vaccine	Shortness of Breath / Fast Heartbeat / Panic Attack / Shoulder Pain / Anxiety / Frozen Extremities / Dizziness	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / COVID Pneumonia	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / Fever/ Headache / Body Ache	1
COVID-19 Vaccine	Shortness of Breath / Fatigue / Heavy Limbs	1
COVID-19 Vaccine	Shortness of Breath / Fever / Chills / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Racing Heartbeat	1
COVID-19 Vaccine	Shortness of Breath / Rapid Heartbeat / Dizziness	1

COVID-19 Vaccine	Shortness of Breath / Rash / Migraine	1
COVID-19 Vaccine	Shortness of Breath / Shivering / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Sore Muscles / Chest Pains / Flu Like Symptoms	1
COVID-19 Vaccine	Shortness of Breath / Swelling / High Blood Pressure / Heart Problems / Anxiety	1
COVID-19 Vaccine	Shortness of Breath / Wheezing / Chest Pain	1
COVID-19 Vaccine	Shortness of Breath / Heart Palpitations/ Leg Pain / Dizziness	1
COVID-19 Vaccine	Shoulder / Arm Injury	9
COVID-19 Vaccine	Shoulder Injury	25
COVID-19 Vaccine	Shoulder Pain	8
COVID-19 Vaccine	Sinusitis	1
COVID-19 Vaccine	SIRVA	7
COVID-19 Vaccine	Sixth Nerve Palsy	1
COVID-19 Vaccine	Skin and Gum Sensitivity / Anal Fistulas	1
COVID-19 Vaccine	Skin Rash / Muscle Weakness	1
COVID-19 Vaccine	Slurred Speech / Face Drooping / Tingling in Face	1
COVID-19 Vaccine	Small Fiber Neuropathy	2
COVID-19 Vaccine	Spasms / Cramps / Swollen Tongue / Shingles	1
COVID-19 Vaccine	Spinal Meningitis	1
COVID-19 Vaccine	Spongiotic Dermatitis	1
COVID-19 Vaccine	Stevens Johnson Syndrome	1
COVID-19 Vaccine	Stiff Neck / Migraine	1
COVID-19 Vaccine	Stroke	28
COVID-19 Vaccine	Stroke / Blood Clots	1
COVID-19 Vaccine	Stroke / Death	1
COVID-19 Vaccine	Stroke Like Symptoms	3

COVID-19 Vaccine	Stroke Like Symptoms / Collapsed Lung	1
COVID-19 Vaccine	Subacromial Bursitis	1
COVID-19 Vaccine	Subarachnoid Hemorrhage / Seizure / Traumatic Brain Injury	1
COVID-19 Vaccine	Subcutaneous Sarcoidosis	1
COVID-19 Vaccine	Sudden Hearing Loss (SSHL) / Sudden Deafness	1
COVID-19 Vaccine	Sulphur Taste and Smell	1
COVID-19 Vaccine	Supraventricular Tachycardia	2
COVID-19 Vaccine	Swelling	1
COVID-19 Vaccine	Swelling / Burning / Inflammation	1
COVID-19 Vaccine	Swelling / Headaches / Bad Dreams / Drowsiness / Stroke / Low Blood Pressure	1
COVID-19 Vaccine	Swelling / Hives	1
COVID-19 Vaccine	Swelling / Rash / Skin Peeling	1
COVID-19 Vaccine	Swelling / Trouble Breathing	1
COVID-19 Vaccine	Swollen and Inflamed Lymph Nodes / Cystic Nodule	1
COVID-19 Vaccine	Swollen Ankle	1
COVID-19 Vaccine	Swollen Feet, Arms and Tongue	1
COVID-19 Vaccine	Swollen Finger	1
COVID-19 Vaccine	Swollen Hands / Tingling / Nerve Pain / Eczema	1
COVID-19 Vaccine	Swollen Lymph Nodes	4
COVID-19 Vaccine	Swollen Lymph Nodes / Asthma	1
COVID-19 Vaccine	Syncope	4
COVID-19 Vaccine	Syncope / Concussion / Cheek Bone & Teeth Fractures	1
COVID-19 Vaccine	Syncope / Confusion / Headaches	1

COVID-19 Vaccine	Syncope / Face Head and Nose Injury	1
COVID-19 Vaccine	Syncope / Hypertension / Ischemic Tachycardia / Non-Ischemic Cardiomyopathy / Non-sustained Ventricular Tachycardia / Atrial Fibrillation / Pulmonary Interstitial Edema	1
COVID-19 Vaccine	Systemic Inflammatory Response Syndrome (SIRS)	2
COVID-19 Vaccine	Tachycardia	5
COVID-19 Vaccine	Tachycardia / Diaphoretic	1
COVID-19 Vaccine	Tachycardia / Hypertension / Palpitation	1
COVID-19 Vaccine	Tachycardia / Shortness of Breath / Tremors / Hot Flashes / Paresthesia / Blurred Vision / Near Syncope / Muscle Tension	1
COVID-19 Vaccine	Throat Inflammation / Muscle Pain / Fever	1
COVID-19 Vaccine	Throat Swelling	1
COVID-19 Vaccine	Throat Swelling / Itching / Redness / Heavy Menstrual Flow / Headache / Fatigue / Numbness / Arm Pain	1
COVID-19 Vaccine	Throat Swelling / Tachycardia / Heart Palpitations	1
COVID-19 Vaccine	Throat Tongue Hand and Arm Swelling / Lesions	1
COVID-19 Vaccine	Thrombocytopenia	3
COVID-19 Vaccine	Thrombocytopenia / Cellulitis	1
COVID-19 Vaccine	Thrombosis	2
COVID-19 Vaccine	Thrush / Swollen Tongue, Plate and Gums	1
COVID-19 Vaccine	Thrush / Symptoms of Systemic Inflammatory Response Syndrome	1
COVID-19 Vaccine	Thyroid Storm	1
COVID-19 Vaccine	TIA Stroke	2

COVID-19 Vaccine	Tingling / Numbness / Paralysis	1
COVID-19 Vaccine	Tingling / Rash / Rapid Heartbeat	1
COVID-19 Vaccine	Tinnitus	9
COVID-19 Vaccine	Tinnitus / Hearing Loss	2
COVID-19 Vaccine	Tinnitus / Vertigo / Vomiting	1
COVID-19 Vaccine	Tonsillitis	1
COVID-19 Vaccine	Transient Global Amnesia	1
COVID-19 Vaccine	Transverse Myelitis	8
COVID-19 Vaccine	Transverse Myelitis / GBS	1
COVID-19 Vaccine	Trigger Finger	1
COVID-19 Vaccine	TTS	1
COVID-19 Vaccine	Ulcerative Colitis	1
COVID-19 Vaccine	Unable to Breathe / Unresponsive	1
COVID-19 Vaccine	Unable to Walk	1
COVID-19 Vaccine	Unresponsive / Foaming at Mouth / Low Blood Pressure	1
COVID-19 Vaccine	Unresponsive / Tachycardia / Low Heart Rate / Pain	1
COVID-19 Vaccine	UTI	1
COVID-19 Vaccine	Vaccine Induced Axillary Lymphadenopathy	1
COVID-19 Vaccine	Vasculitis	1
COVID-19 Vaccine	Vasculitis / Trouble Swallowing Food / Weakness	1
COVID-19 Vaccine	Vasovagal Syncope	4
COVID-19 Vaccine	Vertigo / Brain Fog	1
COVID-19 Vaccine	Vertigo / Dizziness / Lightheadedness / Low Energy	1
COVID-19 Vaccine	Vertigo / Migraine	1
COVID-19 Vaccine	Vertigo / Vomiting	1
COVID-19 Vaccine	Vestibular Neuritis	4

COVID-19 Vaccine	Vestibular Neuritis / Migraines / Severe Inflammation	1
COVID-19 Vaccine	Vestibular Neuritis / Tinnitus	1
COVID-19 Vaccine	Vision Loss	5
COVID-19 Vaccine	Vision Loss / Fainted	1
COVID-19 Vaccine	Vision Loss / Muscle Spasms / High Blood Pressure	1
COVID-19 Vaccine	Vision Loss/ Balance Issues / Headaches / Fatigue / Vertigo / Chest Tightness	1
COVID-19 Vaccine	Vocal Cord Dysfunction	1
COVID-19 Vaccine	Vomiting / Fever / Dehydration / Rapid Heartbeat	1
COVID-19 Vaccine	Vomiting / Shortness of Breath	1
COVID-19 Vaccine	Vomiting / Shortness of Breath / Tachycardia	1
COVID-19 Vaccine	VTE / DVT	1
COVID-19 Vaccine	Weakness / Breathing Difficulty / Difficulty Swallowing and Chewing / Double Vision	1
COVID-19 Vaccine	Weakness / Difficulty Walking	2
COVID-19 Vaccine	Weakness / Difficulty Walking / Extreme Body Aches	1
COVID-19 Vaccine	Weakness / Fatigue / Fever / Muscle Pain / Headaches / Chills / Cold Sweats / Cognitive Issues / Chest Tightness / Shortness of Breath / Numbness	1
COVID-19 Vaccine	Weakness / Fatigue / Heart and Blood Pressure Issues	1
COVID-19 Vaccine	Wheezing / Coughing / Shortness of Breath / Blurred Vision	1
COVID-19 Vaccine	Wheezing / Lightheadedness / Dizziness / Metal Taste in Mouth	1

COVID-19 Vaccine	Wheezing / Muscle Weakness / Migraine / Hypertension	1
COVID-19 Vaccine / Remdesivir	Death	1
Decadron / Remdesivir	Death	1
Delay or Failure to Provide Proper Medication and Treatment	Death	1
Dexamethasone	Death	1
Dexamethasone / Doxycycline / Piperacillin-Tazobactam	Death	1
Dexamethasone / Remdesivir	Death	1
Extracorporeal Membrane Oxygenation Machine	Death	1
Failure to Abide by COVID-19 Regulations	Death	1
Hydroxychloroquine	Death	18
Hydroxychloroquine / Azithromycin	Death	1
Hydroxychloroquine / Dexamethasone / Dialysis	Death	1
Hydroxychloroquine / Fentanyl / Intubation	Death	1
Hydroxychloroquine / Medrol	Death	1
Hydroxychloroquine / Odansetron	Death	1
Hydroxychloroquine / Remdesivir	Death	5
Hydroxychloroquine / Remdesivir / Convalescent Plasma	Death	1
Hydroxychloroquine / Sarilumab	Death	1
Hydroxychloroquine / Solu-Medrol / Tocilizumab	Death	2
Intubation	Death	4
Mefloquine	Dizziness / Hearing Loss / PTSD / Tinnitus / Temperature Sensitivity	1
N-95 Mask	Shoulder Injury	1
N-95 Mask / PPE	COVID	1
N-95 Mask / Ventilator	Death	1
Not Specified	Bell’s Palsy	1
Not Specified	Death	133
Not Specified	DVT / Chest Pain / Neurologic Symptoms	1
Not Specified	Not Specified	3
Not Specified	Pancreatitis	1
Not Specified	TIA Stroke	1

Not Specified	Ulcer / Myopathy	1
Not Specified	Weakness / Difficulty Walking	1
Oxygen / Prednisone	Death	1
Oxygen / Remdesivir	Death	1
Permavir / Remdesivir / Steroids	Death	1
Remdesivir	Death	29
Remdesivir	Renal Failure / Pulmonary Embolism / Pneumonia	1
Remdesivir / Tocilizumab	Death	1
Stay At Home Order / Masks / No Elective Surgeries	Attempted Murder / Assault / Damage to Multiple Body Parts	1
Tylenol	Death	1
Ventilator	Collapsed Lung	1
Ventilator	Death	138
Ventilator / Acute Blood Loss / Blood Transfusion	Death	1
Ventilator / Anakinra / Ceftriaxone / Convalescent Plasma / Heparin / Medrol / Steroids / Tocilizumab	Death	1
Ventilator / Antibiotics / Intubation / Sedation	Death	1
Ventilator / Antiviral Medications	Death	2
Ventilator / Antivirals / Convalescent Plasma / Neglect / Pneumonia	Death	1
Ventilator / Azithromycin	Death	10
Ventilator / Azithromycin	Respiratory Failure / Kidney Failure	1
Ventilator / Azithromycin / BiPap / Dialysis / Plaquenil / Tocilizumab	Death	2
Ventilator / Azithromycin / BiPap / Remdesivir	Death	1
Ventilator / Azithromycin / Ceftriaxone	Death	1
Ventilator / Azithromycin / Ceftriaxone / Dialysis / Heparin / Steroids	Death	1
Ventilator / Azithromycin / Ceftriaxone / Dialysis / Heparin / Vancomycin	Death	1
Ventilator / Azithromycin / Convalescent Plasma	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Decadron / Dialysis	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Medrol / Remdesivir	Death	2
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Dexamethasone / Remdesivir / Tocilizumab	Death	2

Ventilator / Azithromycin / Convalescent Plasma / Dialysis / Remdesivir / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir	Death	3
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Convalescent Plasma / Remdesivir / Steroids	Death	2
Ventilator / Azithromycin / Convalescent Plasma / Steroids	Death	1
Ventilator / Azithromycin / Decadron / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Decadron / Remdesivir / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Azithromycin / Dexamethasone	Death	4
Ventilator / Azithromycin / Dexamethasone / Dialysis	Death	1
Ventilator / Azithromycin / Dexamethasone / Dialysis / Solumedrol	Death	1
Ventilator / Azithromycin / Dexamethasone / Medrol / Remdesivir	Death	1
Ventilator / Azithromycin / Dexamethasone / Methylprednisolone / Remdesivir	Death	2
Ventilator / Azithromycin / Dexamethasone / Remdesivir	Death	6
Ventilator / Azithromycin / Dexamethasone / Remdesivir / Steroids	Death	1
Ventilator / Azithromycin / Dialysis / Remdesivir / Solu-Medrol	Death	1
Ventilator / Azithromycin / Heparin	Death	1
Ventilator / Azithromycin / Ivermectin / Methylprednisolone / Remdesivir	Death	1
Ventilator / Azithromycin / Ivermectin / Remdesivir	Death	1
Ventilator / Azithromycin / Methylprednisolone	Death	1
Ventilator / Azithromycin / Remdesivir	Death	7
Ventilator / Azithromycin / Sedation	Death	1
Ventilator / Azithromycin / Tocilizumab	Death	1
Ventilator / BiPap	Death	2
Ventilator / BiPAP / COVID-19 Medications	Death	1
Ventilator / BiPAP / COVID-19 Medications / Oxygen	Death	1
Ventilator / BiPap / Remdesivir	Death	4
Ventilator / BiPap / Soliris / Remdesivir	Death	1
Ventilator / Ceftriaxone / Remdesivir	Death	1
Ventilator / Convalescent Plasma	Death	6
Ventilator / Convalescent Plasma / Covid-19 Medications	Death	1

Ventilator / Convalescent Plasma / Decadron / Intubation / Lorazepam	Death	1
Ventilator / Convalescent Plasma / Dexamethasone / Remdesivir	Death	1
Ventilator / Convalescent Plasma / Dialysis	Death	1
Ventilator / Convalescent Plasma / Intubation	Death	1
Ventilator / Convalescent Plasma / Remdesivir	Death	6
Ventilator / Convalescent Plasma / Remdesivir / Tocilizumab	Death	1
Ventilator / Covid-19 Medications	Death	666
Ventilator / COVID-19 Medications / COVID-19 Test	Death	1
Ventilator / COVID-19 Medications / Oxygen	Death	1
Ventilator / COVID-19 Vaccine	Death	6
Ventilator / CPAP	Death	1
Ventilator / Dexamethasone	Death	1
Ventilator / Dexamethasone / Dialysis	Death	1
Ventilator / Dexamethasone / Dialysis / Methylprednisolone / Remdesivir	Death	1
Ventilator / Dexamethasone / Remdesivir	Death	3
Ventilator / Dexamethasone / Remdesivir / Tocilizumab	Death	1
Ventilator / Dialysis	Death	1
Ventilator / Endotracheal Tube	Death	1
Ventilator / Hydroxychloroquine	Death	20
Ventilator / Hydroxychloroquine / Antibiotics / Intubation / PIC Line / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Antibiotics / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin	Death	49
Ventilator / Hydroxychloroquine / Azithromycin / Aztreonam / Dexamethasone / Linezolid	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / BiPap / Convalescent Plasma / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / BiPap / Dialysis / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Convalescent Plasma / Doxycycline / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Dialysis / Heparin / Tocilizumab / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Steroids	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Steroids / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Medrol / Tocilizumab	Death	1

Ventilator / Hydroxychloroquine / Azithromycin / Ceftriaxone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / CPAP / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Dialysis	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Convalescent Plasma / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone / Dialysis / Solu-Medrol / Steroids / Tocilizumab	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dexamethasone / Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis	Death	11
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Heparin / Vasopressin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone / Remdesivir	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Methylprednisolone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Solu-Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Solu-Medrol/ Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Steroids	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Steroids / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Dialysis / Tocilizumab	Death	3
Ventilator / Hydroxychloroquine / Azithromycin / Heparin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Heparin / Medrol / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Medrol / Vancomycin	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone	Death	5
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone / Remdesivir / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Methylprednisolone / Tocilizumab	Death	3
Ventilator / Hydroxychloroquine / Azithromycin / Plaquenil	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Plaquenil / Zithromax	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Remdesivir	Death	19
Ventilator / Hydroxychloroquine / Azithromycin / Remdesivir / Tocilizumab / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Solu-Medrol	Death	2
Ventilator / Hydroxychloroquine / Azithromycin / Solu-Medrol / Tocilizumab	Death	1

Ventilator / Hydroxychloroquine / Azithromycin / Steroids / Medrol / Ceftriaxone / Heparin / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Steroids / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Azithromycin / Tocilizumab	Death	5
Ventilator / Hydroxychloroquine / Ceftriaxone / Convalescent Plasma / Heparin / Medrol / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Ceftriaxone / Heparin	Death	1
Ventilator / Hydroxychloroquine / Ceftriaxone / Heparin / Medrol / Steroids	Death	1
Ventilator / Hydroxychloroquine / Convalescent Plasma	Death	1
Ventilator / Hydroxychloroquine / Convalescent Plasma / Dialysis / Methylprednisolone / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Covid-19 Test	Death	1
Ventilator / Hydroxychloroquine / Dexamethasone / Dialysis	Death	1
Ventilator / Hydroxychloroquine / Dexamethasone / Methylprednisolone / Remdesivir / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Dialysis / Heparin / Vancomycin	Death	1
Ventilator / Hydroxychloroquine / Dialysis / Solu-Medrol	Death	1
Ventilator / Hydroxychloroquine / Heparin / Medrol / Steroids / Vancomycin / Ventilator	Death	1
Ventilator / Hydroxychloroquine / Medrol	Death	1
Ventilator / Hydroxychloroquine / Methylprednisolone	Death	1
Ventilator / Hydroxychloroquine / Methylprednisolone / Remdesivir / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Remdesivir	Death	7
Ventilator / Hydroxychloroquine / Solu-Medrol / Tocilizumab	Death	1
Ventilator / Hydroxychloroquine / Steroids / Tocilizumab	Death	2
Ventilator / Hydroxychloroquine / Z-Pac	Death	1
Ventilator / Intubation	Death	3
Ventilator / Lovenox	Death	1
Ventilator / Permavir / Relenza	Death	1
Ventilator / Plaquenil	Death	1
Ventilator / Remdesivir	Death	31
Ventilator / Remdesivir / Convalescent Plasma	Death	3
Ventilator / Remdesivir / Methylprednisolone	Death	1
Ventilator / Remdesivir / Seasonal Flu Vaccine / Midazolam	Death	1
Ventilator / Remdesivir / Steroids	Death	1
Ventilator / Remdesivir / Tocilizumab	Death	1

Ventilator / Tamiflu	Not Specified	1
Ventilator / Tocilizumab	Death	1
Ventilator / Tranquilizer	Death	1
Total COVID-19		**3,158**

Table 2. CICP Claims Compensated (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure, alleged injury and amount of compensation paid for each compensated CICP claim filed between Fiscal Years 2010 through 2021.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury	Compensation Amount
1	H1N1 Vaccine	Guillain-Barrè Syndrome (GBS)	$2,309.94
2	H1N1 Vaccine	Bursitis	$385.00
3	H1N1 Vaccine	Anaphylaxis	$1,885.44
4	Smallpox Vaccine	Myocarditis	$323,035.75
5	H1N1 Vaccine	Anaphylaxis	$2,995.23
6	H1N1 Vaccine	Shoulder Pain	$182.20
7	H1N1 Vaccine	GBS	$1,762,920.56
8	H1N1 Vaccine	GBS	$185,479.52
9	H1N1 Vaccine	GBS	$15,662.07
10	H1N1 Vaccine	GBS	$106,723.54
11	H1N1 Vaccine	GBS	$210.75
12	H1N1 Vaccine	GBS	$2,360.84
13	H1N1 Vaccine	GBS	$2,364.55
14	H1N1 Vaccine	GBS	$3,534.00
15	H1N1 Vaccine	GBS	$6,966.40
16	H1N1 Vaccine	GBS	$553,945.53
17	H1N1 Vaccine	GBS	$7,623.45
18	H1N1 Vaccine	GBS	$2,295,929.61
19	H1N1 Vaccine	GBS	$13,581.93
20	H1N1 Vaccine	GBS	$27,378.82
21	H1N1 Vaccine	GBS	$5,677.77
22	H1N1 Vaccine	GBS	$127,435.39
23	H1N1 Vaccine	GBS	$30.93
24	H1N1 Vaccine	GBS	$3,500.00

25	H1N1 Vaccine	GBS	$38.00
26	H1N1 Vaccine	GBS	$2,316.00
27	H1N1 Vaccine	GBS	$571,635.25
28	H1N1 Vaccine	GBS	$49,759.00
29	H1N1 Vaccine	GBS	$220.00
Total			**$6,076,087.47**

Table 3. CICP Claims Eligible for Compensation, but No Eligible Reported Losses or Expenses (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was eligible for compensation, but did not have eligible reported losses or expenses.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number ⬍	Alleged Countermeasure ⬍	Alleged Injury ⬍
1	H1N1 Vaccine	GBS
2	H1N1 Vaccine	GBS
3	Smallpox Vaccine	Myocarditis
4	H1N1 Vaccine	Anaphylaxis
5	H1N1 Vaccine	GBS
6	Smallpox Vaccine	Serum sickness
7	H1N1 Vaccine	Herpes Zoster Outbreak
8	H1N1 Vaccine	GBS
9	H1N1 Vaccine	GBS
10	H1N1 Vaccine	GBS

Table 4. CICP Claims Denied Compensation Because Required Medical Records Were Not Submitted (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was denied compensation because the requester did not submit any required medical records, which may include not submitting any of the medical records specified in their Authorization for Use or Disclosure of Health Information Form(s) submitted to the Program. When this occurs, CICP staff notify the requester and provide them an opportunity to submit the appropriate medical records. However, if the appropriate medical records are not received, CICP staff are unable to conduct a medical review of the claim. If medical records documenting the alleged injury are received, the claim will proceed to a medical review even if incomplete after the requester has had an opportunity to submit the additional appropriate medical records.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number ⬍	Alleged Countermeasure ⬍	Alleged Injury ⬍
1	H1N1 vaccine	Anaphylaxis
2	H1N1 vaccine	Rash (Arm/Shoulder)

Number	Alleged Countermeasure	Alleged Injury
3	H1N1 vaccine	Rash (Upper Torso/Scalp)
4	H1N1 vaccine	Flu Symptoms
5	H1N1 vaccine	Not Specified
6	H1N1 vaccine	Flu Symptoms
7	H1N1 vaccine	Flu Symptoms
8	H1N1 vaccine	Not Specified
9	H1N1 vaccine	Fever/ Difficulty Breathing
10	H1N1 vaccine	Anaphylaxis
11	H1N1 vaccine	Flu Symptoms
12	H1N1 vaccine	Fever / Vomiting / Shortness of Breath
13	H1N1 vaccine	GBS
14	H1N1 vaccine	Neurologic symptoms
15	H1N1 vaccine	Flu Symptoms
16	H1N1 vaccine	Polyarthritis
17	H1N1 vaccine	Gastroenteritis
18	H1N1 vaccine	Allergic Reaction
19	H1N1 vaccine	Miscarriage
20	H1N1 vaccine	Bell's Palsy
21	H1N1 vaccine	Weakness/ Elevated Blood Pressure
22	H1N1 vaccine	Arm Pain
23	H1N1 vaccine	Hematoma
24	H1N1 vaccine	Rapid Heartbeat / Dizziness
25	H1N1 vaccine	Allergic Reaction
26	H1N1 vaccine	Allergic Reaction
27	H1N1 vaccine	Allergic Reaction
28	H1N1 vaccine	Allergic Reaction
29	H1N1 vaccine	Not Specified
30	H1N1 vaccine	Allergic Reaction
31	H1N1 vaccine	Transverse Myelitis
32	H1N1 vaccine	Allergic Reaction
33	H1N1 vaccine	Allergic Reaction

Number	Alleged Countermeasure	Alleged Injury
34	H1N1 vaccine	GBS
35	H1N1 vaccine	Not Specified
36	H1N1 vaccine	Lymph Node Enlargement
37	H1N1 vaccine	Myalgias
38	H1N1 vaccine	Not Specified
39	H1N1 vaccine	Idiopathic Thrombocytopenic Purpura (ITP)
40	H1N1 vaccine	Anaphylactic Shock
41	H1N1 vaccine	Not Specified
42	H1N1 vaccine	Allergic Reaction
43	H1N1 vaccine	Weakness/ Neurologic Issues
44	H1N1 vaccine	Miscarriage
45	H1N1 vaccine	Rotator Cuff Tear
46	H1N1 vaccine	Numbness/ Swelling
47	H1N1 vaccine	GBS
48	H1N1 vaccine	Edema/ Itching/ Rash/ Skin Lesions/ Weight loss
49	H1N1 vaccine	Autoimmune Encephalopathy
50	H1N1 vaccine	Cyst
51	H1N1 vaccine	Allergic Reaction
52	H1N1 vaccine	Wheezing / Fever
53	H1N1 vaccine	Fever/ Headache/ Severe Pain
54	H1N1 vaccine	Miscarriage
55	H1N1 vaccine	Miscarriage
56	H1N1 vaccine	Allergic Reaction
57	H1N1 vaccine	Bell’s Palsy
58	H1N1 vaccine	GBS
59	H1N1 vaccine	Not Specified
60	H1N1 vaccine	GBS
61	H1N1 vaccine	Obsessive Behavior/ Depression
62	H1N1 vaccine	Not Specified
63	H1N1 vaccine	GBS
64	H1N1 vaccine	Miscarriage

Number	Alleged Countermeasure	Alleged Injury
65	H1N1 vaccine	Diabetes
66	H1N1 vaccine	Allergic Reaction
67	H1N1 vaccine	Neurologic symptoms
68	H1N1 vaccine	Pain at Injection Site
69	H1N1 vaccine	Miscarriage
70	H1N1 vaccine	Fatigue / Spasms
71	H1N1 vaccine + Tamiflu + Relenza	Severe Cough
72	H1N1 vaccine	Pain / Weakness
73	H1N1 vaccine	Severe Cough
74	H1N1 vaccine	Autoimmune Reaction
75	H1N1 vaccine	Not Specified
76	H1N1 vaccine	Allergic Reaction
77	H1N1 vaccine	Headaches / Severe Pain
78	H1N1 vaccine	Headaches / Severe Pain
79	H1N1 vaccine	Peripheral Neuropathy / Paresthesia
80	H1N1 vaccine	Not Specified
81	H1N1 vaccine	Pain / Numbness
82	H1N1 vaccine	Difficulty Breathing
83	H1N1 vaccine	Rash
84	H1N1 vaccine	Not Specified
85	H1N1 vaccine	Miscarriage
86	H1N1 vaccine	Numbness / Pain
87	H1N1 vaccine	Not Specified
88	H1N1 vaccine	Viral Illness
89	H1N1 vaccine	Pneumonia
90	H1N1 vaccine	Not Specified
91	H1N1 vaccine	Hives
92	H1N1 vaccine	Shoulder Severe Pain
93	H1N1 vaccine	Shoulder Pain
94	H1N1 vaccine	Heart Arrhythmia / Syncope/ Seizures/ Stroke

Number	Alleged Countermeasure	Alleged Injury
95	H1N1 vaccine	Not Specified
96	H1N1 vaccine	Polymyositis/ Fibromyalgia
97	H1N1 vaccine	Breathing Issues
98	H1N1 vaccine	Neurologic symptoms
99	H1N1 vaccine	Not Specified
100	H1N1 vaccine	Pain / Nausea / Numbness
101	H1N1 vaccine	GBS
102	H1N1 vaccine	Neuropathy / Dizziness / Fatigue
103	H1N1 vaccine	Not Specified
104	H1N1 vaccine	Not Specified
105	H1N1 vaccine	Not Specified
106	H1N1 vaccine	Not Specified
107	H1N1 vaccine	Rotator Cuff Tear / Tendonitis / Nerve Damage
108	H1N1 vaccine	Flu Symptoms
109	H1N1 vaccine	Not Specified
110	H1N1 vaccine	Death
111	H1N1 vaccine	Paralysis
112	H1N1 vaccine	Immobility / Shoulder pain
113	H1N1 vaccine	Rheumatoid Arthritis / Raynaud's Syndrome
114	H1N1 vaccine	Breathing Issues / Coughing
115	H1N1 vaccine	Pain at Injection Site
116	H1N1 vaccine	Shoulder Pain / Weakness
117	H1N1 vaccine	Pain / Spasms
118	H1N1 vaccine	Numbness / Soreness / Spasms
119	H1N1 vaccine	GBS
120	H1N1 vaccine	Weakness / Numbness
121	Anthrax vaccine	GBS
122	H1N1 vaccine	Paralysis / Numbness / Pain
123	H1N1 vaccine	Paralysis / Pain
124	H1N1 vaccine	Chest Pain

Number	Alleged Countermeasure	Alleged Injury
125	H1N1 vaccine	Bradycardia / Postural Orthostatic Tachycardia Syndrome (POTS) / Hypertension / Headache
126	Smallpox vaccine	GBS
127	Smallpox vaccine	Myocarditis
128	Smallpox vaccine	Pain / Allergic Reaction
129	Anthrax Vaccine	Encephalitis / Seizures
130	H1N1 vaccine	Not Specified
131	Smallpox vaccine	Allergic Reaction
132	Anthrax vaccine	Allergic Reaction / Nervous system Disorder / Thyroid Cancer
133	H1N1 vaccine	GBS / Death
134	Anthrax vaccine	Myocarditis
135	H7N9 Drug Trial	Heart Palpitations

Table 5. CICP Claims Denied Compensation for Not Meeting the Standard of Proof and/or a Covered Injury Was Not Sustained (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was denied compensation because the standard of proof for causation was not met and/or a covered injury was not sustained. To be eligible for CICP benefits, a requester must show that a covered serious physical injury was sustained as the direct result of the administration or use of a covered countermeasure. **The CICP may only make such determinations based on compelling, reliable, valid, medical and scientific evidence.** A covered injury is a serious physical injury (which, as a general matter, is an injury that warranted hospitalization, whether or not the person was actually hospitalized, or that led to a significant loss of function or disability, whether or not hospitalization was warranted), or death, determined to be:

1. An injury meeting the requirements of a covered countermeasures injury table, unless there is another more likely cause; or
2. An injury (or its health complications) that is the direct result of the administration or use of a covered countermeasure. This includes serious aggravation caused by a covered countermeasure of a pre-existing condition.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	H1N1 vaccine	Headaches/ Breathing Difficulty
2	H1N1 vaccine	Eosinophilic Esophagitis
3	H1N1 vaccine	Allergic Reaction
4	H1N1 vaccine	Hearing Loss
5	H1N1 vaccine	Allergic Reaction
6	H1N1 vaccine	Paralysis / Weakness
7	H1N1 vaccine	Allergic Reaction
8	H1N1 vaccine	ITP
9	H1N1 vaccine	Flu Symptoms

Number	Alleged Countermeasure	Alleged Injury
10	H1N1 vaccine	Flu Symptoms
11	H1N1 vaccine	Abdominal Pain
12	H1N1 vaccine	Acute Cardiopulmonary Arrest
13	H1N1 vaccine	Neuropathy
14	H1N1 vaccine	Transverse Myelitis
15	H1N1 vaccine	Flu Symptoms
16	H1N1 vaccine	Bronchitis
17	H1N1 vaccine	Asthma
18	H1N1 vaccine	Transverse Myelitis
19	H1N1 vaccine	Connective Tissue Disease
20	H1N1 vaccine	Premature Labor
21	H1N1 vaccine	Migraine Headaches
22	H1N1 vaccine	Flu Symptoms
23	H1N1 vaccine	Neuropathy
24	H1N1 vaccine	Fibromyalgia / Groves Disease
25	H1N1 vaccine	Allergic Hepatitis
26	H1N1 vaccine	Allergic Reaction
27	H1N1 vaccine	A-Fib / Difficulty Breathing
28	H1N1 vaccine	Pain / Numbness
29	H1N1 vaccine	GBS
30	H1N1 vaccine	Neuropathy
31	H1N1 vaccine	Acute Disseminated Encephalomyelitis (ADEM)
32	H1N1 vaccine	GBS
33	H1N1 vaccine	GBS
34	H1N1 vaccine	Hyperthyroidism
35	H1N1 vaccine	Upper Respiratory Infection
36	H1N1 vaccine	Paresthesias
37	H1N1 vaccine	GBS
38	H1N1 vaccine	Allergic Reaction
39	H1N1 vaccine	Movement Disorder
40	H1N1 vaccine	Migraine Headaches

Number	Alleged Countermeasure	Alleged Injury
41	H1N1 vaccine	Death
42	H1N1 vaccine	Muscle Strain
43	H1N1 vaccine	Bell's Palsy
44	H1N1 vaccine	Death
45	H1N1 vaccine	Miscarriage
46	H1N1 vaccine	Headaches / Shortness of Breath / Miscarriage
47	H1N1 vaccine	Neurologic symptoms
48	H1N1 vaccine	Not Specified
49	H1N1 vaccine	GBS
50	H1N1 vaccine	GBS
51	H1N1 vaccine	Optic Neuritis
52	H1N1 vaccine	GBS / Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
53	H1N1 vaccine	Allergic Reaction
54	H1N1 vaccine	Miscarriage
55	H1N1 vaccine	Neuropathy
56	H1N1 vaccine	Anaphylactic Shock
57	H1N1 vaccine	Stroke
58	H1N1 vaccine	Weakness / Heart Palpitations
59	H1N1 vaccine	Abdominal Pain
60	H1N1 vaccine	Bronchitis / Pneumonia / Shoulder Pain/ Weakness
61	H1N1 vaccine	Seizures / Fatigue
62	H1N1 vaccine	CIDP
63	H1N1 vaccine	Idiopathic Polyneuropathy
64	H1N1 vaccine	Henoch Schonlein Purpura (HSP)
65	H1N1 vaccine	Ocular Migraine
66	H1N1 vaccine	Allergic Reaction
67	H1N1 vaccine	Miscarriage
68	H1N1 vaccine	Myocarditis
69	H1N1 vaccine	Miscarriage
70	H1N1 vaccine	Rash
71	H1N1 vaccine	Pneumonia

Number	Alleged Countermeasure	Alleged Injury
72	H1N1 vaccine	Rash / Hives
73	H1N1 vaccine	Rheumatoid Arthritis / Fatigue / Pain/ Headaches
74	H1N1 vaccine	GBS Symptoms / Nausea
75	H1N1 vaccine	Small Fiber Neuropathy
76	H1N1 vaccine	Small Fiber Neuropathy
77	H1N1 vaccine	Weakness / Low Blood Pressure / Rapid Heartbeat
78	H1N1 vaccine	Seizures
79	H1N1 vaccine	GBS
80	H1N1 vaccine	Hives / Brain Swelling
81	H1N1 vaccine	GBS
82	H1N1 vaccine	Nerve Damage
83	H1N1 vaccine	Peripheral neuropathy
84	H1N1 vaccine	Gastroparesis
85	H1N1 vaccine	Chronic Pain
86	H1N1 vaccine	Fever / Pain / Weakness / Swelling/ Fatigue
87	H1N1 vaccine	Death
88	H1N1 vaccine	Vertigo
89	H1N1 vaccine	Adhesive Capsulitis
90	H1N1 vaccine	Flu
91	H1N1 vaccine	Allergic Reaction
92	H1N1 vaccine	GBS
93	H1N1 vaccine	Miscarriage
94	H1N1 vaccine	Tachycardia
95	H1N1 vaccine	GBS
96	H1N1 vaccine	Weakness/ Swelling
97	H1N1 vaccine	GBS Symptoms
98	H1N1 vaccine	Damage to Auto-Immune System
99	H1N1 vaccine	Pharyngitis / Tachycardia
100	H1N1 vaccine	CIDP
101	H1N1 vaccine	Muscle Pain
102	H1N1 vaccine	Transverse Myelitis

Number	Alleged Countermeasure	Alleged Injury
103	H1N1 vaccine	Bell's Palsy
104	H1N1 vaccine	Pneumonia
105	H1N1 vaccine	Headaches / Paresthesias
106	H1N1 vaccine	Dizziness / Weakness
107	H1N1 vaccine	Numbness / Hypertension/ Brachial Neuritis
108	H1N1 vaccine	CIDP
109	H1N1 vaccine	Transverse Myelitis
110	H1N1 vaccine	Anaphylaxis / Pneumonia
111	H1N1 vaccine	ITP
112	H1N1 vaccine	Multiple Sclerosis
113	H1N1 vaccine	Asthma / Pneumonia
114	H1N1 vaccine	Serum Sickness
115	H1N1 vaccine	Pain / Weakness
116	H1N1 vaccine	Tingling
117	H1N1 vaccine	Indigestion
118	H1N1 vaccine	Brachial Plexus
119	H1N1 vaccine	Eye Problems
120	H1N1 vaccine	GBS
121	H1N1 vaccine	Fibromyalgia
122	H1N1 vaccine	Wheezing / Fatigue / Weakness
123	H1N1 vaccine	Paralysis
124	H1N1 vaccine	Conversion Disorder
125	H1N1 vaccine	Flu-like Symptoms
126	H1N1 vaccine	Brain Lesions
127	H1N1 vaccine	CIDP
128	H1N1 vaccine	Polyarthritis
129	H1N1 vaccine	Shoulder Pain/ Ovarian Cyst
130	H1N1 vaccine	Neuropathy
131	H1N1 vaccine	Delusions
132	H1N1 vaccine	Pain / Nausea / Weakness / Numbness / Fatigue
133	H1N1 vaccine	Myocarditis

Number	Alleged Countermeasure	Alleged Injury
134	H1N1 vaccine	Vasculitis / Renal Failure
135	H1N1 vaccine	GBS
136	H1N1 vaccine	GBS
137	H1N1 vaccine	GBS
138	H1N1 vaccine	Boil
139	H1N1 vaccine	CIDP
140	H1N1 vaccine	Acute Disseminated Encephalomyelitis (ADEM)
141	H1N1 vaccine	Encephalitis / Seizures
142	H1N1 vaccine	Tinnitus / Hearing Loss
143	H1N1 vaccine	Reflex Sympathetic Dystrophy, Meningitis
144	H1N1 vaccine	Dyspnea / Severe Pain
145	H1N1 vaccine	Transverse Myelitis
146	H1N1 vaccine	Myalgias
147	H1N1 vaccine	Anaphylactic Shock
148	H1N1 vaccine	Fever / Loss of Consciousness
149	H1N1 vaccine	Weakness / Severe Pain / Migraine
150	H1N1 vaccine	GBS
151	H1N1 vaccine	Weakness / Neurologic Issues
152	H1N1 vaccine	GBS
153	H1N1 vaccine	GBS
154	H1N1 vaccine	GBS
155	H1N1 vaccine	Acute Kidney Injury
156	H1N1 vaccine	Chronic Fatigue Syndrome
157	H1N1 vaccine	Neurologic symptoms
158	H1N1 vaccine	Death
159	H1N1 vaccine	Death
160	H1N1 vaccine	Serum Sickness
161	H1N1 vaccine	Weakness / Numbness / Pain
162	H1N1 vaccine	High Blood Pressure
163	H1N1 Vaccine	Hearing Loss
164	H1N1 vaccine	Seizures / Encephalopathy

Number	Alleged Countermeasure	Alleged Injury
165	H1N1 vaccine	Numbness / Pain / Tremors/ Nausea
166	H1N1 vaccine	Speech Loss
167	H1N1 vaccine	Parethesias
168	H1N1 vaccine	Numbness / Weakness / Fatigue
169	H1N1 vaccine	Weakness / Swelling
170	H1N1 vaccine	Hearing Loss
171	H1N1 vaccine	Severe Pain
172	H1N1 vaccine	Rash / Swelling / Fever
173	H1N1 vaccine	Swelling/ Miscarriage / Rash/ Swollen Lymph Nodes
174	H1N1 vaccine	Allergic Reaction
175	H1N1 vaccine	Henoch Schonlein Purpura (HSP)
176	H1N1 vaccine	Autonomic Dysfunction
177	H1N1 vaccine	Bell's Palsy
178	H1N1 vaccine	Arm Pain / Edema / Blurry Vision
179	H1N1 vaccine	Brain Elisions / Weakness / Paralysis
180	H1N1 vaccine	Acquired Hemophilia A
181	H1N1 vaccine	Acute Transverse Myelitis
182	H1N1 vaccine	Seizures
183	H1N1 vaccine	Seizures
184	H1N1 vaccine	GBS
185	H1N1 vaccine	GBS
186	H1N1 vaccine	Seizures
187	H1N1 vaccine	GBS
188	H1N1 vaccine	GBS
189	H1N1 vaccine	Headaches / Tremors / Nausea / Dizziness
190	H1N1 vaccine	Serum Sickness
191	H1N1 vaccine	Death
192	H1N1 vaccine	Encephalopathy
193	H1N1 vaccine	Pain
194	H1N1 vaccine	Seizures
195	H1N1 vaccine	Not Specified

Number	Alleged Countermeasure	Alleged Injury
196	H1N1 vaccine	Fever
197	H1N1 vaccine	GBS
198	H1N1 vaccine	GBS
199	H1N1 vaccine	Brachial Neuritis
200	H1N1 vaccine	Bronchitis
201	H1N1 vaccine	Cellulitis
202	H1N1 vaccine	Rheumatoid Arthritis
203	H1N1 vaccine	Interstitial Cystitis / Celiac Sprue
204	H1N1 vaccine	CIDP
205	H1N1 vaccine	Fibromyalgia / Lyme Disease
206	H1N1 vaccine	GBS
207	H1N1 vaccine	Bell's Palsy
208	H1N1 vaccine	Rash
209	H1N1 vaccine	GBS
210	H1N1 vaccine	Myositis
211	H1N1 vaccine	Leg Pain / Weakness / Anxiety
212	H1N1 vaccine	CIDP
213	H1N1 vaccine	GBS
214	Anthrax vaccine	Undifferentiated Connective Tissue Disease
215	Anthrax vaccine	Headaches
216	H5N1 vaccine	Esophagitis
217	H1N1 vaccine	Seizures / Brain Damage
218	Anthrax vaccine	Allergic Reaction
219	Smallpox vaccine / Anthrax vaccine	Hypertension
220	Anthrax vaccine	Serum Sickness
221	Smallpox vaccine	Death
222	Smallpox vaccine	Pain / Itching
223	Smallpox vaccine	Hand Tingling, Headache, Chest Pain, Drowsiness, Disorientation
224	Anthrax vaccine	Myalgia

Alleged COVID-19 Countermeasures

Number	Alleged Countermeasure	Alleged Injury

Number	Alleged Countermeasure	Alleged Injury
225	Ventilator	Death
226	COVID-19 Vaccine	Swelling of the Tongue and Throat, Difficulty Speaking and Swallowing and Dizziness
227	COVID-19 Vaccine	SIRVA

Table 6. CICP Ineligible Claims due to Missing the Filing Deadline (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was ineligible because the Request for Benefits (claim) was not filed within the 1-year filing deadline. The claim must be filed within 1 year after the date of the administration or use of the covered countermeasure alleged to have caused the injury or within 1 year after the effective date of the establishment of, or amendment to, a countermeasure injury table.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	Anthrax vaccine	Epilepsy/ Seizures
2	Anthrax vaccine	Pain/ Blisters
3	H1N1 vaccine	Anxiety Attack
4	H1N1 vaccine	Bilateral Brachial plexus
5	H1N1 vaccine	Bradycardia
6	H1N1 vaccine	CIDP
7	H1N1 vaccine	Fatigue / Fibromyalgia / Brachial Neuritis
8	H1N1 vaccine	GBS
9	H1N1 vaccine	GBS
10	H1N1 vaccine	Miscarriage
11	H1N1 vaccine	Myopericarditis
12	H1N1 vaccine	Narcolepsy
13	H1N1 vaccine	Neurologic symptoms
14	H1N1 vaccine	Not Specified
15	H1N1 Vaccine	Numbness / Amputation
16	H1N1 vaccine	Numbness / Metallic Taste
17	H1N1 vaccine	Optic Neuritis
18	H1N1 vaccine	Pain / Weakness
19	H1N1 vaccine	Paralysis
20	H1N1 vaccine	Paralysis / Severe Pain
21	H1N1 vaccine	Pericarditis
22	H1N1 vaccine	Pneumonia / Edema/ Paralysis/ Confusion

Number	Alleged Countermeasure	Alleged Injury
23	H1N1 vaccine	Postural Orthostatic Tachycardia Syndrome (POTS)
24	H1N1 vaccine	Rash
25	H1N1 vaccine	Rheumatoid Arthritis
26	H1N1 vaccine	Seizures
27	H1N1 vaccine	Severe Arm Pain
28	H1N1 vaccine	Severe Pain
29	H1N1 vaccine	Shoulder Pain
30	H1N1 vaccine	Vision Problems / Paralysis
31	H1N1 vaccine	Weakness / Severe Pain
32	H1N1 vaccine	Weakness / Neurologic Issues
33	H1N1 vaccine	Vasculitis / Tendonitis / Polymyalgia Rheumatica
34	H1N1 vaccine	Transverse Myelitis
35	Smallpox vaccine	Pericarditis
36	Smallpox vaccine	Not Specified
37	Smallpox vaccine	Heart Swelling / High Blood Pressure/ Paralysis
38	Smallpox Vaccine, Anthrax Vaccine	Severe Ulcerative Colitis

Table 7. Ineligible Claims for Products Not Covered by the CICP (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that was ineligible because the Request for Benefits (claim) alleged an injury from a product that the CICP does not cover.

Please note that the number column within the tables are not assigned numbers for a particular claim, but reflect the number of listed items in a given table. Further details concerning the table contents are provided below.

Number	Alleged Countermeasure	Alleged Injury
1	1976 H1N1 vaccine	GBS
2	1976 H1N1 vaccine	GBS
3	Pre-Prep Act Anthrax vaccine	Fatigue/ Fibromyalgia/ Depression/ Lesions
4	Pre-Prep Act Anthrax vaccine	Migraine Headaches
5	Pre-Prep Act Anthrax vaccine	Migraine Headaches
6	Pre-Prep Act Anthrax vaccine	Migraine Headaches / Pain / Diarrhea
7	Pre-Prep Act Anthrax vaccine	Nerve Disorder / Sleep Disorder
8	Pre-Prep Act Anthrax vaccine	Neuropathy / Central Nervous System Demyelinating Disease / Inflammatory Joint Disease / Fatigue
9	Pre-Prep Act Anthrax vaccine	Not Specified

Number	Alleged Countermeasure	Alleged Injury
10	Pre-Prep Act Anthrax vaccine	Diarrhea / Fatigue / Asthma
11	Pre-Prep Act Anthrax vaccine	Myofacial Pain Syndrome / SLE Lupus / Scoliosis / SI Joint Dysfunction / IBS Syndrome / Night Sweats / Psychosis
12	DTAP, MMR vaccines	Minimal Change Disease
13	DTAP, Polio, and Haemoplilus Influenzae B vaccines	Seizures / Infantile Spasms / Delayed Development
14	Human Papillomavirus (HPV) Vaccine	Enlarged Lymph Nodes/ Spleen and Liver
15	HPV vaccine	Neurologic Symptoms
16	Influenza / Pneumococcal Vaccines	Allergic Reaction
17	Japanese Encephalitis vaccine	Weakness/ Neurologic Issues
18	Meningococcal vaccine	Double Vision
19	Meningococcal vaccine	Shoulder Pain
20	Pneumococcal Vaccine	Pain/ Fever/ Inflammation
21	Pneumococcal vaccine	Fainting
22	Pneumococcal vaccine	Not Specified
23	Seasonal Flu vaccine	Arm Pain
24	Seasonal Flu vaccine	Arm Swelling
25	Seasonal Flu vaccine	Bipolar Disorder/ Depression
26	Seasonal Flu vaccine	Birth Defects
27	Seasonal Flu vaccine	Calcified Tendons/ Arthritis symptoms
28	Seasonal Flu vaccine	CIDP
29	Seasonal Flu vaccine	Death
30	Seasonal Flu vaccine	Flu-like Symptoms
31	Seasonal Flu vaccine	Flu-like Symptoms
32	Seasonal Flu vaccine	Frozen Shoulder Syndrome
33	Seasonal Flu vaccine	GBS
34	Seasonal Flu vaccine	GBS
35	Seasonal Flu vaccine	Headache / Tremors / Fever
36	Seasonal Flu vaccine	Laryngitis
37	Seasonal Flu vaccine	Neurologic symptoms
38	Seasonal Flu vaccine	Not Specified
39	Seasonal Flu vaccine	Numbness / Weakness / Headaches/ Double Vision

Number	Alleged Countermeasure	Alleged Injury
40	Seasonal Flu vaccine	Paralysis
41	Seasonal Flu vaccine	Paralysis / Pain
42	Seasonal Flu vaccine	Paralysis / Pain
43	Seasonal Flu vaccine	Paresthesia / Weakness / Tremors
44	Seasonal Flu vaccine	Severe Arm Pain
45	Seasonal Flu vaccine	Shoulder Pain
46	Seasonal Flu vaccine	Shoulder Pain
47	Seasonal Flu vaccine	Stevens Johnson Syndrome
48	Seasonal Flu vaccine	GBS
49	Shingles vaccine	Immobility / Fibromyalgia / Depression
50	Shingrix vaccine	Pain
51	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Boils / Stroke / High Blood Pressure / Arthritis
52	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Not Specified
53	Pre-Prep Act Smallpox Vaccine / Pre-Prep Act Anthrax vaccine	Organic Brain Syndrome / Neuropathy
54	Tetanus, Diphtheria, Acellular Pertussis (TDAP) Vaccine	Arm Pain

Table 8. CICP Ineligible Claims Due to Not Alleging Any Countermeasure Administration or Use (Fiscal Years 2010 – 2021) As of October 1, 2021

This table displays the alleged countermeasure and alleged injury for each CICP claim filed between Fiscal Years 2010 through 2021 that is ineligible because the Request for Benefits did not allege the administration or use of any countermeasure.

Number	Alleged Countermeasure	Alleged Injury
1	Not Specified	Weakness/ Neurologic Issues

Date Last Reviewed: October 2021

Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections

Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon

doi: https://doi.org/10.1101/2021.08.24.21262415

Abstract

Background Reports of waning vaccine-induced immunity against COVID-19 have begun to surface. With that, the comparable long-term protection conferred by previous infection with SARS-CoV-2 remains unclear.

Methods We conducted a retrospective observational study comparing three groups: (1)SARS-CoV-2-naïve individuals who received a two-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine, (2)previously infected individuals who have not been vaccinated, and (3)previously infected *and* single dose vaccinated individuals. Three multivariate logistic regression models were applied. In all models we evaluated four outcomes: SARS-CoV-2 infection, symptomatic disease, COVID-19-related hospitalization and death. The follow-up period of June 1 to August 14, 2021, when the Delta variant was dominant in Israel.

breakthrough infection with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant (*P*<0.001) for symptomatic disease as well. When allowing the infection to occur at any time before vaccination (from March 2020 to February 2021), evidence of waning natural immunity was demonstrated, though SARS-CoV-2 naïve vaccinees had a 5.96-fold (95% CI, 4.85 to 7.33) increased risk for breakthrough infection and a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic disease. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalizations compared to those that were previously infected.

Conclusions This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. Individuals who were both previously infected with SARS-CoV-2 and given a single dose of the vaccine gained additional protection against the Delta variant.

Competing Interest Statement

The authors have declared no competing interest.

Funding Statement

There was no external funding for the project.

Author Declarations

I confirm all relevant ethical guidelines have been followed, and any necessary IRB and/or ethics committee approvals have been obtained.

Yes

The details of the IRB/oversight body that provided approval or exemption for the research described are given below:

This study was approved by the MHS (Maccabi Healthcare Services) Institutional Review Board (IRB). Due to the retrospective design of the study, informed consent was waived by the IRB, and all identifying details of the participants were removed before computational analysis.

All necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived.

I understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).

Yes

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

Yes

Footnotes

- The authors declare they have no conflict of interest.
- **Funding:** There was no external funding for the project.

Paper in collection COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

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Preprint discussion sites covering this article:

2019 Novel Coronavirus Research Compendium, 25 Aug 2021

PUBPEER PubPeer, 30 Aug 2021

Blog posts linking to this article:

ZERO ANTHROPOLOGY, 01 Dec 2021

“Two weeks to flatten the curve,” is what we heard across Canada1 just after March 11, 2020, when the World Health Organization…

Booster Shots - latimes.com, 27 Nov 2021

In people who got a booster shot, levels of neutralizing antibodies exceeded the peak that followed two doses of COVID-19…

Shedding of Infectious SARS-CoV-2 Despite Vaccination

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Abstract

The SARS-CoV-2 Delta variant might cause high viral loads, is highly transmissible, and contains mutations that confer partial immune escape [1,2]. Outbreak investigations suggest that vaccinated persons can spread Delta [3,4]. We compared RT-PCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin 29 June through 31 July 2021 and tested with a qualitative assay by a single contract laboratory. Specimens came from residents of 36 counties, most in southern and southeastern Wisconsin, and 81% of cases were not associated with an outbreak. During this time, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and state immunization records (**Supplemental Figure 1**).

Main text

We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%; **Figure 1A**) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people (**Figure 1B**).

Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing (**Figure 1C**). Ct values <25 were detected in 7 of 24 unvaccinated (29%; CI: 13-51%) and 9 of 11 fully vaccinated asymptomatic individuals (82%; CI: 48-97%), and 158 of 232 unvaccinated (68%, CI: 62-74%) and 156 of 225 fully vaccinated (69%; CI: 63-75%) symptomatic individuals. Time from symptom onset to testing did not vary by vaccination status (p=0.40; **Supplemental Figure 2**). Infectious virus was detected in the sole specimen tested from an asymptomatic fully vaccinated individual. Although few asymptomatic individuals were sampled, these results indicate that even asymptomatic, fully vaccinated people might shed infectious virus.

Combined with other studies [2–5], these data indicate that vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-

2 is frequently found even in vaccinated persons when specimen Ct values are low. The inclusion of viruses from Pango lineages B.1.617.2, AY.2, and AY.3, and multiple counties without a linking outbreak, indicate that Delta-lineage SARS-CoV-2 can achieve low Ct values consistent with transmissibility in fully vaccinated individuals across a range of settings. Vaccinated and unvaccinated persons should get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19. Continued adherence to non-pharmaceutical interventions during periods of high community transmission to mitigate spread of COVID-19 remain important for both vaccinated and unvaccinated individuals.

Figure

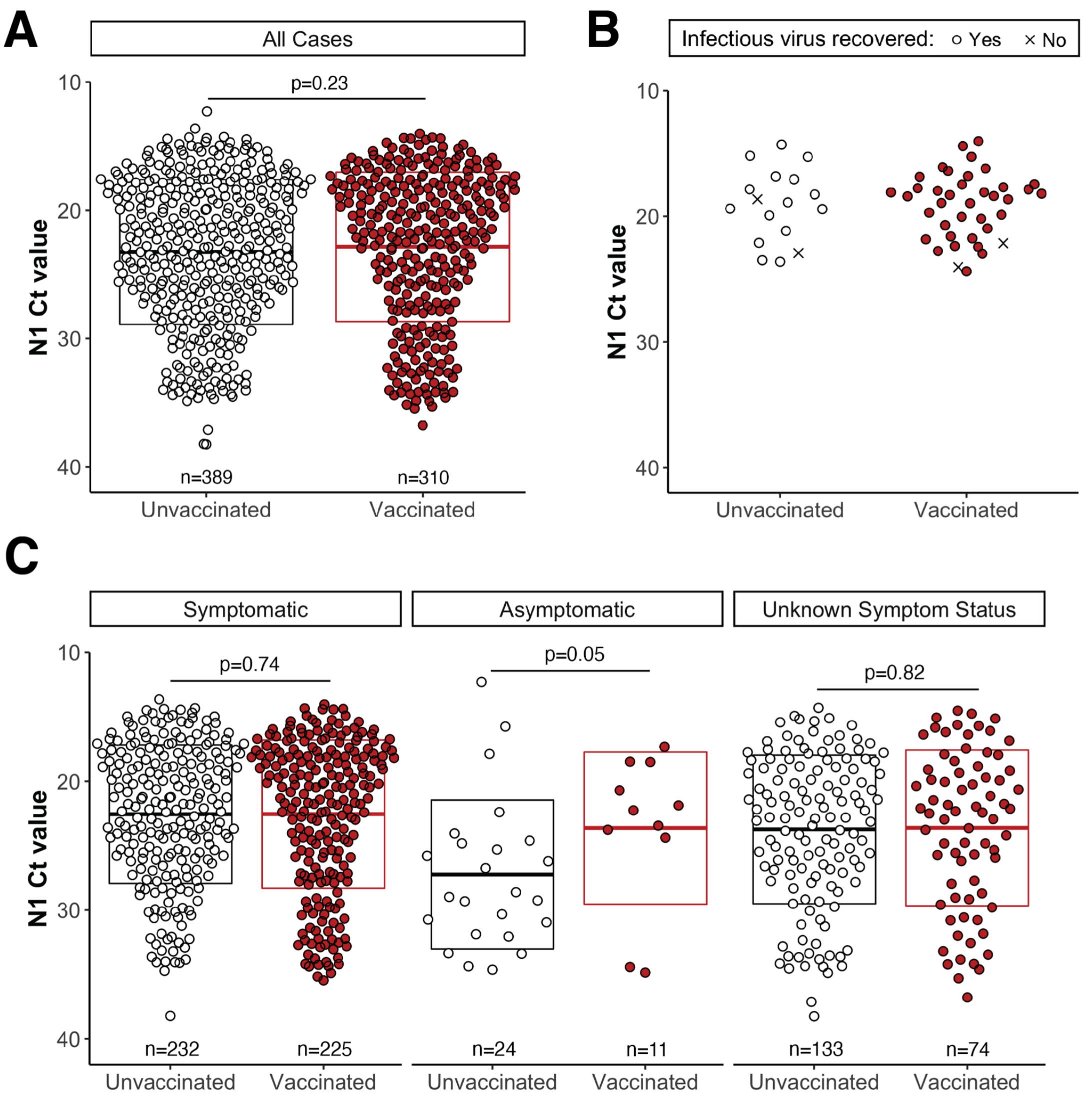


Figure 1. Individuals infected with SARS-CoV-2 despite full vaccination have low Ct values and shed infectious virus. A. Ct values for SARS-CoV-2-positive specimens grouped by vaccination status. RT-PCR was performed by Exact Sciences Corporation, responsible for over 10% of all PCR tests in Wisconsin during this period, using a qualitative diagnostic assay targeting the SARS-CoV-2 N gene (oligonucleotides identical to CDC's N1 primer and probe set) that has been authorized for emergency use by FDA (https://www.fda.gov/media/138328/download). **B.** Infectiousness was determined for a subset of N1 Ct-matched specimens with Ct <25 by inoculation onto Vero E6 TMPRSS2 cells and determining presence of cytopathic effects (CPE) after 5 days in culture. Specimens were selected by N1 Ct-matching between fully vaccinated and not fully vaccinated persons, then specimens from persons with unknown vaccination status were excluded from the analysis. Circles indicate presence of CPE; 'X' indicates no CPE detected. **C.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals who were symptomatic or asymptomatic, or those whose symptom status was not determined, at the time of testing. In **A** and **C**,

boxplots represent mean N1 Ct values +/- one standard deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

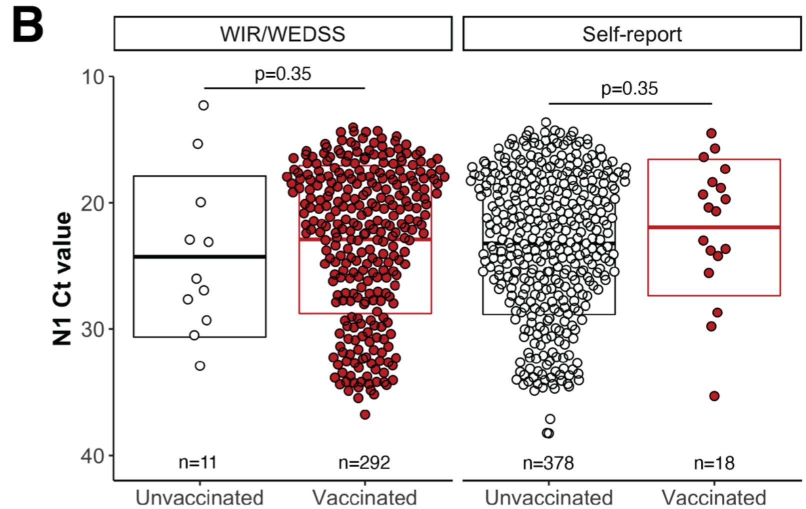
Supplemental materials

Supplemental figure 1

A

Vaccinated per WIR or WEDSS	Vaccinated per self-report: Yes	Vaccinated per self-report: No
Yes	124	33
No	0	8

B



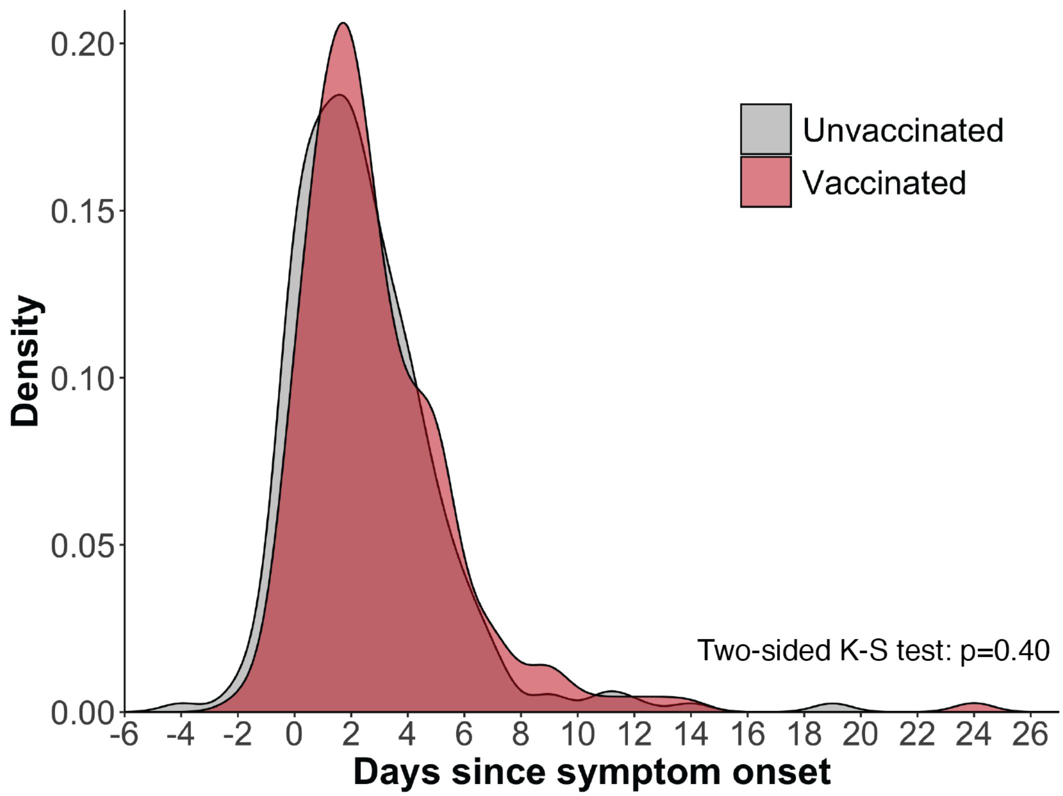
Supplemental figure 1. Concordance between self-reported vaccination status and the Wisconsin Immunization Registry (WIR) or Wisconsin Electronic Disease Surveillance System (WEDSS). For all individuals, vaccination status was determined using WIR/WEDSS electronic registries when data were available. Individuals were identified as unvaccinated at the time of testing if WIR/WEDSS data indicated receipt of a first SARS-CoV-2 vaccine dose after the test date.

Individuals were considered fully vaccinated based on WIR/WEDSS data if the registries indicated receipt of a final vaccine dose at least 14 days prior to testing. For individuals whose vaccination status could not be verified in WIR/WEDSS, self-reported data collected at the time of testing were used. Individuals were considered unvaccinated based on self-report only if there was an explicit declaration of unvaccinated status in the self-reported data. Individuals were considered fully vaccinated based on self-report if they fulfilled all of the following criteria: (1) indicated that they had received a COVID vaccine prior to testing; (2) indicated that they did not require another vaccine dose; and (3) reported a date of last vaccine dose that was at least 14 days prior to testing.

Specimens lacking data on vaccination status were excluded from the study. Specimens from partially vaccinated individuals (incomplete vaccine series, or <14 days post-final dose) were also excluded. Fully vaccinated status was determined by WIR/WEDSS for 292 specimens and by self-reported data for 18. Unvaccinated status was determined by WIR/WEDSS for 11 and by self-reported data by 378. **A.** Of the 699 specimens with vaccination status available from at least one source, 165 specimens had data available from both sources. For self-reporting, under-reporting of full vaccination status (33/157) was more common than over-reporting (0/124). **B.** N1 Ct values for SARS-CoV-2-positive specimens grouped by vaccination status for individuals whose vaccination status was determined by WIR/WEDDS or by self-reported data. Boxplots represent mean N1 Ct values +/- one standard

deviation. P-values were calculated by comparing mean Ct values by independent two-group Mann-Whitney U tests.

Supplemental figure 2



Supplemental figure 2. Density distributions of unvaccinated and vaccinated specimen collection dates by day since symptom onset. Day 0 on the x-axis denotes self-reported day of symptom onset. Negative values for days indicate specimen collection prior to symptom onset. Symptom onset data were available for n=263 unvaccinated cases and n=232 vaccinated cases.

Conflict of interest

The authors declare no conflicting interests.

Ethics statement

Per the University of Wisconsin-Madison IRB, this project qualifies as public health surveillance activities as defined in the Common Rule, 45 CFR 46.102(l)(2). As such, the project is not deemed to be research regulated under the Common Rule and therefore, does not require University of Wisconsin-Madison IRB review and oversight.

The opinions expressed by authors contributing to this journal do not necessarily reflect the opinions of the Centers for Disease Control and Prevention or the institutions with which the authors are affiliated.

Data availability

Data and processing workflows are available at https://go.wisc.edu/p22l16. To protect potentially personally identifiable information, the publicly available dataset contains only PCR Ct values, vaccine status, symptom status, culture status, and days from symptom onset to testing for each specimen.

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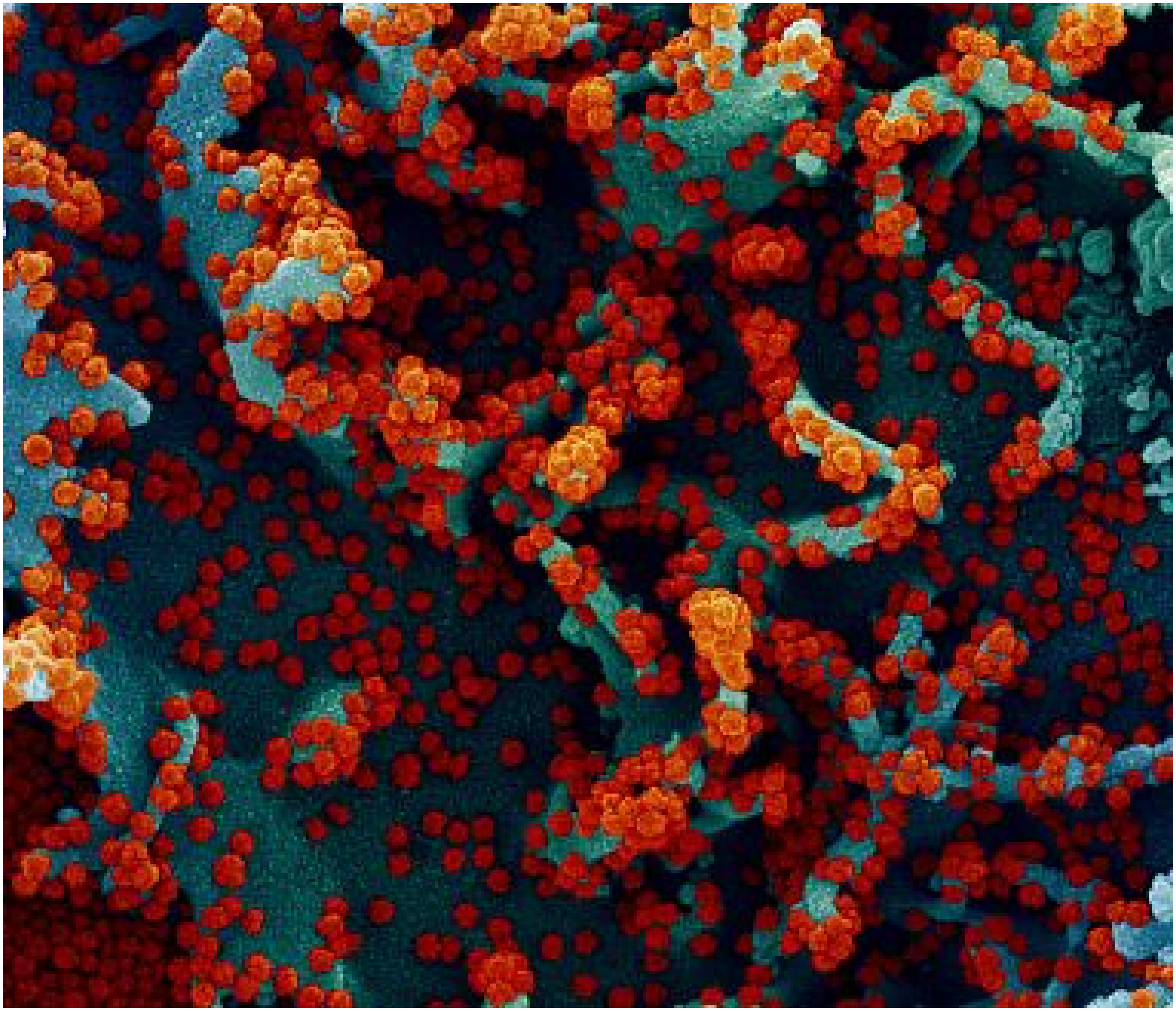
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January 26, 2021

Lasting immunity found after recovery from COVID-19

At a Glance

- The immune systems of more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection.
- The results provide hope that people receiving SARS-CoV-2 vaccines will develop similar lasting immune memories after vaccination.



Colorized scanning electron micrograph of a cell, isolated from a patient sample, that is heavily infected with SARS-CoV-2 virus particles (red). *NIAID Integrated Research Facility, Fort Detrick, Maryland*

After people recover from infection with a virus, the immune system retains a memory of it. Immune cells and proteins that circulate in the body can recognize and kill the pathogen if it's encountered again, protecting against disease and reducing illness severity.

This long-term immune protection involves several components. Antibodies—proteins that circulate in the blood—recognize foreign substances like viruses and neutralize them. Different types of T cells help recognize and kill pathogens. B cells make new antibodies when the body needs them.

All of these immune-system components have been found in people who recover from SARS-CoV-2, the virus that causes COVID-19. But the details of this immune response and how long it lasts after infection have been unclear. Scattered reports of reinfection with SARS-CoV-2 have raised concerns that the immune response to the virus might not be durable.

To better understand immune memory of SARS-CoV-2, researchers led by Drs. Daniela Weiskopf, Alessandro Sette, and Shane Crotty from the La Jolla Institute for Immunology analyzed immune cells and antibodies from almost 200 people who had been exposed to SARS-CoV-2

and recovered.

Time since infection ranged from six days after symptom onset to eight months later. More than 40 participants had been recovered for more than six months before the study began. About 50 people provided blood samples at more than one time after infection.

The research was funded in part by NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI). Results were published on January 6, 2021, in *Science*.

The researchers found durable immune responses in the majority of people studied. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset. As seen in previous studies, the number of antibodies ranged widely between individuals. But, promisingly, their levels remained fairly stable over time, declining only modestly at 6 to 8 months after infection.

Virus-specific B cells increased over time. People had more memory B cells six months after symptom onset than at one month afterwards. Although the number of these cells appeared to reach a plateau after a few months, levels didn't decline over the period studied.

Levels of T cells for the virus also remained high after infection. Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus. These cells help coordinate the immune response. About half the participants had CD8+ T cells, which kill cells that are infected by the virus.

As with antibodies, the numbers of different immune cell types varied substantially between individuals. Neither gender nor differences in disease severity could account for this variability. However, 95% of the people had at least 3 out of 5 immune-system components that could recognize SARS-CoV-2 up to 8 months after infection.

"Several months ago, our studies showed that natural infection induced a strong response, and this study now shows that the responses last," Weiskopf says. "We are hopeful that a similar pattern of responses lasting over time will also emerge for the vaccine-induced responses."

—by Sharon Reynolds

Related Links

- Experimental Coronavirus Vaccine Highly Effective (https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective)
- Antibodies and T Cells Protect Against SARS-CoV-2 (https://www.nih.gov/news-events/nih-research-matters/antibodies-t-cells-protect-against-sars-cov-2)
- Immune Cells for Common Cold May Recognize SARS-CoV-2 (https://www.nih.gov/news-events/nih-research-matters/immune-cells-common-cold-may-recognize-sars-cov-2)
- Potent Neutralizing Antibodies Target New Regions of Coronavirus Spike (https://www.nih.gov/news-events/nih-research-matters/potent-neutralizing-antibodies-target-new-regions-coronavirus-spike)
- Potent Antibodies Found in People Recovered from COVID-19 (https://www.nih.gov/news-events/nih-research-matters/potent-antibodies-found-people-recovered-covid-19)
- Novel Coronavirus Structure Reveals Targets for Vaccines and Treatments (https://www.nih.gov/news-events/nih-research-matters/novel-coronavirus-structure-reveals-targets-vaccines-treatments)
- Coronavirus (COVID-19) (https://covid19.nih.gov/)
- Coronavirus Prevention Network (https://www.coronaviruspreventionnetwork.org/)

- Coronavirus (COVID-19) (https://www.coronavirus.gov/)

References: Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Dan JM, Mateus J, Kato Y, Hastie KM, Yu ED, Faliti CE, Grifoni A, Ramirez SI, Haupt S, Frazier A, Nakao C, Rayaprolu V, Rawlings SA, Peters B, Krammer F, Simon V, Saphire EO, Smith DM, Weiskopf D, Sette A, Crotty S. *Science*. 2021 Jan 6:eabf4063. doi: 10.1126/science.abf4063. Online ahead of print. PMID: 33408181.

Funding: NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI); La Jolla Institute for Immunology; John and Mary Tu Foundation; Bill and Melinda Gates Foundation; Mastercard; Wellcome; Emergent Ventures; Collaborative Influenza Vaccine Innovation Centers; JPB Foundation; Cohen Foundation; Open Philanthropy Project.

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SARS-CoV-2 infection of the inner ear

Autoimmune response found in many with COVID-19

Common drug may have potential for treating Alzheimer's disease

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U.S. Department of Health and Human Services

The Vaccine Adverse Event Reporting System (VAERS) Results

Vaccine Type	Events Reported	Percent (of 24,671)
ADENOVIRUS TYPE 4 &7 VACCINE, LIVE ORAL (ADEN_4_7)	1	0.00%
ANTHRAX VACCINE (ANTH)	10	0.04%
CHOLERA VACCINE (CHOL)	3	0.01%
COVID19 VACCINE (COVID19)	26,311	106.65%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (DTAP)	26	0.11%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE (DTAPIPV)	7	0.03%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + HEPATITIS B + INACTIVATED POLIOVIRUS VACCINE (DTAPHEPBIP)	12	0.05%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE + INACTIVATED POLIOVIRUS VACCINE + HAEMOPHILUS B CONJUGATE VACCINE (DTAPIPVHIB)	19	0.08%
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE (DTP)	1	0.00%
DIPHTHERIA AND TETANUS TOXOIDS, PEDIATRIC (DT)	2	0.01%
EBOLA ZAIRE VACCINE (EBZR)	2	0.01%
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	24	0.10%
HEPATITIS A (HEPA)	17	0.07%
HEPATITIS B VACCINE (HEP)	33	0.13%
HUMAN PAPILLOMAVIRUS (TYPES 6, 11, 16, 18) RECOMBINANT VACCINE (HPV4)	12	0.05%
HUMAN PAPILLOMAVIRUS (TYPES 6, 11,16, 18, 31, 33, 45, 52, 58) RECOMBINANT VACCINE (HPV9)	52	0.21%
INFLUENZA (H1N1) MONOVALENT (INJECTED) (FLU(H1N1))	1	0.00%
INFLUENZA VIRUS VACCINE, NO BRAND NAME (FLUX(SEASONAL))	27	0.11%
INFLUENZA VIRUS VACCINE, QUADRIVALENT (INJECTED) (FLU4(SEASONAL))	86	0.35%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, ADJUVANT (INJECTED) (FLUA4(SEASONAL))	6	0.02%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, CELL-CULTURE-DERIVED (INJECTED) (FLUC4(SEASONAL))	6	0.02%
INFLUENZA VIRUS VACCINE, QUADRIVALENT, RECOMBINANT (INJECTED) (FLUR4(SEASONAL))	10	0.04%
INFLUENZA VIRUS VACCINE, TRIVALENT (INJECTED) (FLU3(SEASONAL))	11	0.04%
INFLUENZA VIRUS VACCINE, TRIVALENT, ADJUVANT (INJECTED) (FLUA3(SEASONAL))	10	0.04%
INFLUENZA VIRUS VACCINE, TRIVALENT, CELL-CULTURE-DERIVED (INJECTED) (FLUC3(SEASONAL))	1	0.00%
INFLUENZA(H1N1) MONOVALENT, UNKNOWN MANUFACTURER (FLUX(H1N1))	1	0.00%
JAPANESE ENCEPHALITIS VIRUS VACCINE, INACTIVATED, ADSORBED (JEV1)	1	0.00%
MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE (MMR)	35	0.14%
MEASLES, MUMPS, RUBELLA, AND VARICELLA VACCINE (PROQUAD) (MMRV)	9	0.04%
MENINGOCOCCAL B VACCINE (MENB)	11	0.04%
MENINGOCOCCAL POLYSACCHARIDE VACCINE (MEN)	3	0.01%
MENINGOCOCCAL VACCINE (MENACTRA) (MNQ)	11	0.04%
PNEUMOCOCCAL VACCINE, POLYVALENT (PPV)	26	0.11%
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	46	0.19%
POLIOVIRUS VACCINE INACTIVATED (IPV)	6	0.02%
POLIOVIRUS VACCINE TRIVALENT, LIVE, ORAL (OPV)	1	0.00%
RABIES VIRUS VACCINE (RAB)	15	0.06%
ROTAVIRUS (NO BRAND NAME) (RVX)	2	0.01%
ROTAVIRUS VACCINE, LIVE, ORAL (RV1)	6	0.02%
ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT (RV5)	19	0.08%
TETANUS AND DIPHTHERIA TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (BOOSTRIX/ADACEL) (TDAP)	36	0.15%
TETANUS TOXOID (TTOX)	1	0.00%
TYPHOID VACCINE (TYP)	2	0.01%
VARIVAX-VARICELLA VIRUS LIVE (VARCEL)	16	0.06%
YELLOW FEVER VACCINE (YF)	2	0.01%
ZOSTER VACCINE (VARZOS)	360	1.46%
UNKNOWN VACCINES (UNK)	438	1.78%
Total	**27,737**	**112.43%**

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information. (/wonder/help/vaers.html#Suppress)

Data contains VAERS reports processed as of 10/08/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

Values of Event Category field vary in their availability over time due to changes in the reporting form. The "Emergency Room/Office Visit" value was avaliable only for events reported using the VAERS-1 form, active 07/01/1990 to 06/29/2017. The "Congenital Anomaly/Birth Defect", "Emergency Room", and "Office Visit" values are available only for events reported using the VAERS 2.0 form, active 06/30/2017 to present. These changes must be considered when evaluating count of events for these categories.

About COVID19 vaccines:

- For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/).
- One report may state that the patient received more than one brand of COVID-19 vaccine on the same visit. This is a reporting error, but explains why the total number of reports may not equal the total number of COVID-19 vaccine doses.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Oct 20, 2021 7:38:25 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 10/08/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Oct 20, 2021 7:38:25 PM

Query Criteria:

Date Report Received:	2021
Event Category:	Death; Life Threatening; Permanent Disability
State / Territory:	The United States/Territories/Unknown
Group By:	Vaccine Type
Show Totals:	True
Show Zero Values:	False

From:	Kathy Enking
To:	DPBH StateBOH
Subject:	Public Comment Testimony for 12/3/21 BOH Meeting
Date:	Thursday, December 2, 2021 9:43:27 PM

To the Board of Health,

My name is Kathy Enking, I live in . I am a wife, mother, nurse and Functional medicine practitioner.
I have worked in schools, hospitals and clinics with all ages, children to elderly.

I strongly oppose covid vaccine mandates of any sort for all Nevadans.

Each of the covid vaccines (Pfizer-Bio-NTech, Moderna and Johnson & Johnson) currently available in the United States are authorized under Emergency Use Authorization by the Food & Drug Administration (FDA). Per federal law, EUA products cannot be mandated, require informed consent and can be declined.
The single FDA approved covid vaccine (Pfizer Comirnaty) is not currently available to consumers in the U.S.

A child's risk of severe illness or death from SARS-COV2 is extremely low. In fact, peer reviewed data reviewed all cases of childhood deaths from Covid and in every single case, the child had one or more comorbidities. Adults at risk should work with their doctors to formulate a plan to prevent infection if at risk.
It makes no sense to subject an entire healthy population to mandates and potentially harmful therapies in order to protect another population.

There is a very high injury rate of a serious and debilitating condition, Myocarditis, that is being tracked by VAERS, and proves to be significantly higher than the risk of the disease(ovid-19) that it is meant to protect children from.

It goes without saying that parents should be the only responsible party able to make health decisions and medical choices for their children.
NO medical treatment should be coerced or mandated upon children.

The shots are advertised in a way that the person receiving them will experience a reduction in symptoms and severity of the disease at the onset of illness in the injected person, so far there is no datas supporting this claim. Therefore, the covid vaccination cannot be represented as a "public health" safety measure as it has no
measurable effect on anyone including the person being injected. Protection from the disease is less than 6 months, showing it is ineffective.

College Scholarship opportunities are being given to vaccinated children as young as 5 years old who get their first vaccine by Dec 19. Winners get Tuition, room and board plus money for books and supplies. What is being given to those injured by vaccines?

The vaccine mandate is deceitful coercion, as it had now been stated by Dr. Fauci himself that vaccines do not prevent infection or transmission of SARS-COV2.
The public is being lied to. If you move forward with this, you will be perpetuating a lie and you will be

held accountable.

The continuation of this charade is in serious violation of our human and civil rights and is in effect, totalitarianism.
These mandates also violate the Nuremberg code, forcing treatment without consent.

As long as I have been a nurse, medical treatments have always been a personal choice, and should remain that way.
As long as I have been a parent, I alone make medical decisions for my children.

In truth,

Kathy Enking BSN, NTP

"The health effects of Nrf2 may well become the most extraordinary therapeutic and most extraordinary preventative breakthrough in the history of medicine." - Washington State University

Nevada Board of Health Meeting December 3 2021

Agenda Item 5f

Approval of Compliance Agreement

HOW IS IT THAT THIS COMPLIANCE AGREEMENT WAS SIGNED 9/29/2021 BEFORE BOARD APPROVAL?

They also want a six month period in which they do not have to be licensed to be on school campuses. Starting 9/13 when the agreement was signed without approval by the board on 9/29. The entire thing is looking wrong.

This is a perfect example of no one paying attention to those who think they can just **not follow proper procedures and approve something before the agenda is addressed publicly. If I do not see that this is moved to next meeting with proper notice, I will send this information to the proper authorities.**

Do the parents know you intend to allow this company to establish clinics on their children's school sites? Were they informed and given time to make public comments?

Did you inform the parents that the WHO states that the simple presence of a child on testing or vaccine day is implied consent? Did you inform the parents that if these mobile sites intend to vaccinate in the future and they decide to send their students to school without a written declaration that they wish to exclude their child that the child is at risk of implied consent according to World Health Organization?

Are parents aware that the children of high school age could potentially be vaccinated or tested without parent consent?

I say no to this and table it for the next meeting and give proper notice to parents of these schools.

Let's see … we want to open 11 clinics on high school campuses and have no license or permit…. That's a hard NO

Documents attached: testing adversity/discrimination and affects studies, WHO notice of implied consent if you send your child to school on a clinic day, public notice of court mandated release of Pfizer trial results

Elizabeth Hammack - Henderson, NV

COMMON APPROACHES FOR OBTAINING CONSENT FOR VACCINATION

Current practices of obtaining informed consent for vaccination vary among countries, but can be broadly categorized into three approaches.

1. A formal, written consent process is used, particularly in middle- and high-income countries that have a higher percentage of literate populations and a longer history of providing vaccination to older age groups.[4] Vaccination of this target group may be delivered through school health services. Health authorities inform the parents about the vaccination and written consent from the parent is required to opt-in, i.e. give permission for the older child/adolescent to be vaccinated. Alternatively, a written form is used to allow parents to express non-consent (or refusal) to vaccination of their child. This is known as an opt-out procedure.

2. A verbal consent process, whereby consent is given verbally by the parent after being duly informed about the vaccination. However, this approach can only be used when parents accompany the child to the vaccination.

3. An implied consent process by which parents are informed of imminent vaccination through social mobilization and communication, sometimes including letters directly addressed to the parents. Subsequently, the physical presence of the child or adolescent, with or without an accompanying parent at the vaccination session, is considered to imply consent. This practice is based on the opt-out principle and parents who do not consent to vaccination are expected implicitly to take steps to ensure that their child or adolescent does not participate in the vaccination session. This may include not letting the child or adolescent attend school on a vaccination day, if vaccine delivery occurs through schools.

Implied consent procedures are common practice in many countries. However, when children present for vaccination unaccompanied by their parents, it is challenging to determine whether parents indeed provided consent. Therefore, countries are encouraged to adopt procedures that ensure that parents have been informed and agreed to the vaccination. Comprehensive data on whether the approach countries use to deal with consent has changed or evolved over the last decades is not available.

APPROACHES TO OBTAIN INFORMED CONSENT:

1. Written consent

2. Verbal consent

3. Implied consent



4. A WHO survey in 2012 in 34 selected countries from four regions on consent procedures for vaccination in 6–17 year-olds, found that approximately half of the respondent countries use written consent for vaccination in this age group.

Innova Medical Group Recalls Unauthorized SARS-CoV-2 Antigen Rapid Qualitative Test with Risk of False Test Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- **Innova SARS-CoV-2 Antigen Rapid Qualitative Test** (also distributed under the names Innova COVID-19 Self-Test Kit (3T Configuration), Innova SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration), and Innova SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration))
- **Lot codes:**
  - **25T (25 tests per box) -** U2101750, U2101751, X2006004, X2008001, X2008010, X2009002, X2009004, X2009013, X2009016, X2010004, X2010010, X2011005, X2011006, X2011007, X2011008, X2011009, X2011012, X2011013, X2011015, X2011016, X2011017, X2011025, X2011051, X2011052, X2012001, X2012002, X2012004, X2012005, X2012008, X2101002, X2101004, X2101014, X2101031, X2101038
  - **3T (3 tests per box) -** U2102003, X2012310
  - **7T (7 tests per box) -** U2101748, U2102001, U2102002, X2012711, X2103792
- **Manufacturing Dates:** September 1, 2020 to March 3, 2021
- **Distribution Dates:** November 2, 2020 to March 22, 2021
- **Devices Recalled in the U.S.:** At least 77,339
- **Date Initiated by Firm:** March 24, 2021

Device Description

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test claimed to determine if a person has an active COVID-19 infection. The test used a nasal swab sample and test strip to detect specific proteins, called antigens, from the SARS-CoV-2 virus. If the nasal sample had SARS-CoV-2 antigens, a colored test line should have appeared on the test strip, indicating that the person

should not have appeared on the test strip. The test has not been authorized, cleared, or approved by FDA for commercial distribution in the United States.

Reason for Recall

Innova Medical Group is recalling its SARS-CoV-2 Antigen Rapid Qualitative Test. Labeling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during the clinical studies of the tests. The performance characteristics of the test have not been adequately established, presenting a risk of false results.

- **False-negative results** may lead to delayed diagnosis or inappropriate treatment of SARS-CoV-2, which may cause patient harm including serious illness and death. False-negative results can also lead to further spread of the SARS-CoV-2 virus, including when presumed negative patients are grouped into cohorts in health care, long-term care, and other facilities based on false test results.
- **False-positive results** could lead to a delay in the correct diagnosis and the initiation of an appropriate treatment for the actual cause of patient illness, which could be another life-threatening disease that is not SARS-CoV-2. False-positive results could also lead to further spread of the SARS-CoV-2 virus when presumed positive patients are grouped into cohorts based on false test results.

Who May Be Affected

- People who were tested using these devices
- Health care providers who may have access to and use these tests or whose patients have used these tests
- Organizers of large testing programs, such as on college campuses, who may be using and distributing these tests for diagnostic use

What to Do

On April 23, 2021, Innova Medical Group sent all affected device users an Urgent Medical Device Recall letter. The letter provided the following information:

- Do not use these tests to screen for or diagnose COVID-19.
- Identify and remove all affected tests from inventory.
- Either destroy the tests by placing them in the trash or return the tests using the FedEx return label that was included with the letter Innova sent to its customers.

destroyed or returned tests.

The FDA also recommends:

- **Test users and caregivers:** Talk to your health care provider if you think you were tested with the Innova SARS-CoV-2 Antigen Rapid Qualitative Test and you have concerns about your test results.
- **Health care providers:** If the test was given less than two weeks ago, consider retesting your patients using a different SARS-CoV-2 diagnostic test if you suspect an inaccurate result. If testing was performed more than two weeks ago and there is no reason to suspect current SARS-CoV-2 infection, it is not necessary to retest.
- **Testing program organizers:** Notify participants in your testing program to discontinue diagnostic use of these tests and to use an FDA-authorized test to continue testing. For listings of FDA-authorized tests, see:
    - FDA-Authorized Molecular Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
    - FDA-Authorized Antigen Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
- Report any problems you experience with the Innova SARS-CoV-2 Antigen Rapid Test to the FDA, including suspected false results.

For more information, please see the FDA's June 2021 safety communication, Stop Using Innova SARS-CoV-2 Antigen Rapid Qualitative Test (/medical-devices/safety-communications/stop-using-innova-medical-group-sars-cov-2-antigen-rapid-qualitative-test-fda-safety-communication).

Contact Information

Customers with questions about this recall should contact Linda Weinreb at Linda.Weinreb@innovamedgroup.com (mailto:Linda.Weinreb@innovamedgroup.com) or call 747-494-0852.

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event

Risk of False Results with the Curative SARS-Cov-2 Test for COVID-19: FDA Safety Communication

> The Curative, Inc., Curative SARS-Cov-2 Assay (originally authorized as the Korvalabs, Inc. Curative-Korva SARS-Cov-2 Assay) Emergency Use Authorization was revoked at the company's request effective July 15, 2021, because the company is now using different EUA-authorized tests for the testing offered at its laboratories. The test that is the subject of this safety communication is no longer being offered and is no longer authorized for emergency use by the FDA.

Date Issued: January 4, 2021

The U.S. Food and Drug Administration (FDA) is alerting patients and health care providers of the risk of false results, particularly false negative results, with the Curative SARS-Cov-2 test. Risks to a patient of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

To reduce the risk of false negative results, it is important to perform the test in accordance with its authorization and as described in the authorized labeling, e.g., the Fact Sheet for Healthcare Providers (/media/137087/download). When the test is not performed in accordance with its authorization or as described in the authorized labeling, there is a greater risk that the results of the test may not be accurate.

Important Recommendations for Health Care Providers, Patients, and Caregivers

- Be aware of the important information regarding the use of the Curative SARS-Cov-2 test, which is described in the test's authorized labeling, including the following:
    - Collection of nasal swabs and oral fluid specimens is limited to symptomatic individuals within 14 days of COVID-19 symptom onset.
    - Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.
    - A negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

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suspect an inaccurate result was given *recently* by the Curative SARS-Cov-2 test. If testing was performed more than two weeks ago, and there is no reason to suspect current SARS-Cov-2 infection, it is not necessary to retest.

- **Patients and caregivers:** Talk to your health care provider if you think you were tested with the Curative SARS-Cov-2 test (the test name is displayed on this test's authorized Fact Sheets and, generally, the Fact Sheets must be provided with test result reports) and you have concerns about your test results.
- Report any problems you experience with the Curative SARS-Cov-2 test to the FDA, including suspected inaccurate results.

Device Description

The Curative SARS-Cov-2 Assay is a real-time RT-PCR test used to detect SARS-Cov-2, the virus that causes COVID-19. This test is authorized for prescription-only use. The test is performed by collecting a throat swab, nasopharyngeal swab, nasal swab, or oral fluid specimen from an individual suspected of COVID-19 by their health care provider. Under the Emergency Use Authorization, the specimen is then to be processed at the KorvaLabs, Inc., laboratory, and results are returned to the patient.

Consistent with the test's authorized labeling (/media/137087/download), collection of nasal swabs and oral fluid specimens is limited to individuals who have shown symptoms of COVID-19 within 14 days of onset of the symptoms. Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.

Consistent with the EUA summary (/media/137089/download), negative results for SARS-Cov-2 RNA from oral fluid specimens should be confirmed by testing of another specimen type authorized for use with this test if clinically indicated.

FDA Actions

The FDA regularly monitors the post-authorization use of tests, including reports of problems with test performance or results, and is providing this information to help educate patients, caregivers, and health care providers and reduce the risk of false results.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with a Medical Device

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including problems with test performance or results," through MedWatch (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program), the FDA Safety Information and Adverse Event Reporting program.

Generally, as specified in a test's EUA, device manufacturers and authorized laboratories must comply with applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.

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proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17	175[a]
	18-30	4953
	31-50	13886
	51-64	7884
	65-74	3098
	≥ 75	5214
	Unknown	6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

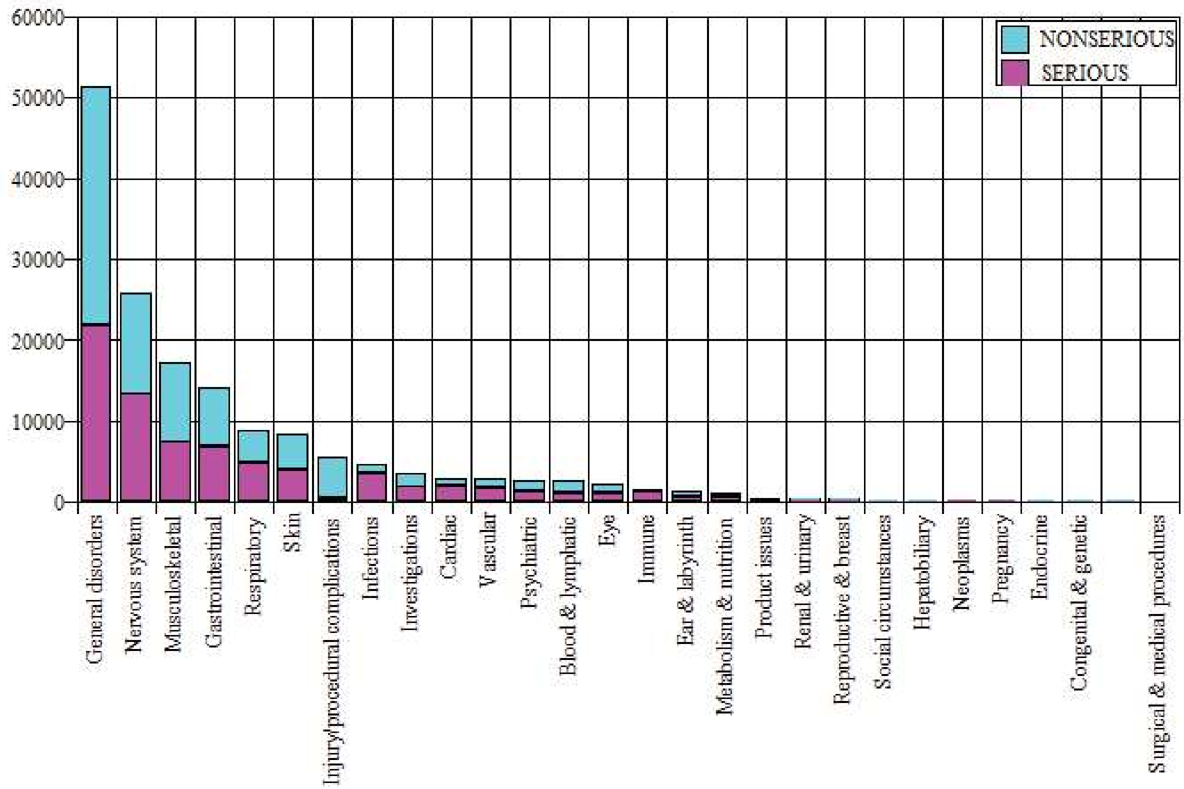


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	MedDRA PT	AEs (AERP%) N = 42086
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

Table 2. Events Reported in ≥2% Cases

MedDRA SOC	MedDRA PT	Cumulatively Through 28 February 2021 AEs (AERP%) N = 42086
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

From:	BRUCE FOSTER
To:	DPBH StateBOH
Subject:	Huge new study shows ZERO Covid deaths of healthy German kids over 4 or adolescents
Date:	Thursday, December 2, 2021 10:12:06 PM

Just a FYI

B. Foster

Huge new study shows ZERO Covid deaths of healthy German kids over 4 or adolescents

The findings, in a nutshell: if you let your healthy child or teenager receive the mRNA Covid vaccine, you are insane

Alex Berenson

Dec 2

German physician-scientists reported Monday that not a single healthy child between the ages of 5 and 18 died of Covid in Germany in the first 15 months of the epidemic.

Not one.

Even including children and adolescents with preexisting conditions, only six in that age range died, the researchers found. Germany is Europe's largest country, with more than 80 million people, including about 10 million school-age children and adolescents.

Serious illness was also extremely rare. The odds that a healthy child aged 5-11 would require intensive care for Covid were about 1 in 50,000, the

researchers found. For older and younger children, the odds were somewhat higher, about 1 in 8,000.

Another eight infants and toddlers died, including five with preexisting conditions. In all, 14 Germans under 18 died of Covid, about one per month. About 1.5 million German children or adolescents were infected with Sars-Cov-2 between March 2020 and May 2021, the researchers found.

“Overall, the SARS-CoV-2-associated burden of a severe disease course or death in children and adolescents is low,” the researchers reported. “This seems particularly the case for 5-11-year-old children without comorbidities.”

The researchers reported their findings in an 18-page paper published to the medrxiv preprint server on Monday.

The data came from a registry Germany established in March 2020 intended to capture all hospitalizations of people under 18 with Covid. All German children’s hospitals, pediatric infectious disease specialists, and pediatric societies were invited to participate.

(SOURCE:
https://www.medrxiv.org/content/10.1101/2021.11.30.21267048v1.full.pdf)

British researchers have posted similar findings, reporting that only six healthy children (including those under 18) out of 12 million died of Covid.

Given the known risks of vaccine-induced myocarditis in young men, the fact that Pfizer tested its mRNA vaccines on barely 3,000 children 5-11 and followed most of them for only weeks after the second dose, the German data again raises the question of how health authorities can possibly justify encouraging children or teenagers to be vaccinated.

But they have.

So parents will have to decide what’s best for their children (at least in those

states that bar vaccine fanatics from trying to vaccinate teenagers without parental consent).

Thanks for subscribing to Unreported Truths. This post is public, so feel free to share it.

Share

From: Robyn Rohlffs
To: DPBH StateBOH
Subject: OPPOSE vaccine mandates
Date: Friday, December 3, 2021 4:21:11 AM

State Board of Health,

I write to express my **strong opposition to vaccine mandates of all types**, particularly for school children and university adults.

Sincerely,
Robyn

From: Lisa Smith
To: DPBH StateBOH
Subject: Public comment testimony for 12/3/21 BOH meeting
Date: Friday, December 3, 2021 7:57:13 AM

Hello Board of Health members,

I oppose covid vaccine mandates or requirements of any sort for all Nevadans. Each of the covid vaccines (Pfizer-Bio-NTech, Moderna and Johnson & Johnson) currently available in the United States are authorized under Emergency Use Authorization by the Food & Drug Administration (FDA). Per federal law, EUA products cannot be mandated, require informed consent and can be declined. The single FDA approved covid vaccine (Pfizer Comirnaty) is not currently available to consumers in the U.S.

I am an educator of special education students and I will not allow the government or anyone to force me to put anything into my body that I do not want. I am prepared to take an early retirement. Last time I checked, my district alone, is short at least 800 licensed educators. We cannot afford to require this shot and weekly tests, pushing our hardworking educators out... causing MORE vacancies.

Furthermore, if you all are thinking about requiring those unvaccinated to test weekly for a virus that continually mutants into variations creating variants and also requiring them to pay for those required tests, that is highly unethical. If you require weekly tests, then you need to absorb the cost, not the people who are exercising their right to choose.

Please do not mandate this shot or weekly tests & definitely without a cost.

Thank you,
Lisa

From:	Shannon Rapp
To:	DPBH StateBOH
Subject:	Public Comment Testimony for 12/3/21 BOH Meeting
Date:	Friday, December 3, 2021 8:20:24 AM

I oppose covid vaccine mandates or requirements of any sort for all Nevadans. Each of the covid vaccines (Pfizer-Bio-NTech, Moderna and Johnson & Johnson) currently available in the United States are authorized under Emergency Use Authorization by the Food & Drug Administration (FDA). Per federal law, EUA products cannot be mandated, require informed consent, and can be declined. The single FDA approved covid vaccine (Pfizer Comirnaty) is not currently available to consumers in the U.S.

Children's risk of severe illness or death from SARS-COV2 is extremely low. The injury rate of just one of the many adverse events from covid vaccination being tracked by VAERS; myocarditis, is significantly higher than the risk of the disease it is meant to protect children from.

Each current covid vaccine available in the U.S. is under Emergency Use Authorization. The only FDA approved covid vaccine is not currently available to consumers in the U.S.

Parents are responsible to make health and medical choices for their children, and no medical treatment should be coerced or mandated upon children.

Because these vaccines do not prevent infection or transmission of SARS-COV2 but are advertised as a way to reduce symptoms and severity of illness in the injected person, covid vaccination cannot be represented as a "public health" measure which has any effect on anyone but the person injected.

Thank you,
Shannon Rapp

From: Jennifer Eaton
To: DPBH StateBOH
Subject: Public Comment Testimony for 12/3/21 BOH Meeting
Date: Thursday, December 2, 2021 5:39:04 PM

I oppose covid vaccine mandates or requirements of any sort for all Nevadans.
Parents are responsible to make health and medical choices for their children, including their college aged children and no medical treatment should be coerced or mandated upon children. Each of the covid vaccines (Pfizer-Bio-NTech, Moderna and Johnson & Johnson) currently available in the United States are authorized under Emergency Use Authorization by the Food & Drug Administration (FDA). Per federal law, EUA products cannot be mandated, require informed consent and can be declined. The single FDA approved covid vaccine (Pfizer Comirnaty) is not currently available to consumers in the U.S.

Jennifer Eaton